US008672885B2

(12) **United States Patent**
Kriesel et al.

(10) **Patent No.: US 8,672,885 B2**
(45) **Date of Patent: *Mar. 18, 2014**

(54) **FLUID DISPENSING DEVICE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 15 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/925,980**

(22) Filed: **Nov. 3, 2010**

(65) **Prior Publication Data**

US 2011/0092904 A1 Apr. 21, 2011

Related U.S. Application Data

(62) Division of application No. 11/725,222, filed on Mar. 14, 2007, now Pat. No. 7,828,772.

(60) Provisional application No. 60/783,182, filed on Mar. 15, 2006.

(51) **Int. Cl.**

A61M 5/20	(2006.01)
A61M 37/00	(2006.01)
A61M 5/00	(2006.01)
A61M 5/14	(2006.01)
A61K 9/22	(2006.01)

(52) **U.S. Cl.**
USPC **604/134**; 604/131; 604/246; 604/247; 604/256; 604/890.1

(58) **Field of Classification Search**
USPC 604/131, 134–136, 151, 153, 207, 211, 604/246–248, 256, 260, 890.1, 891.1
See application file for complete search history.

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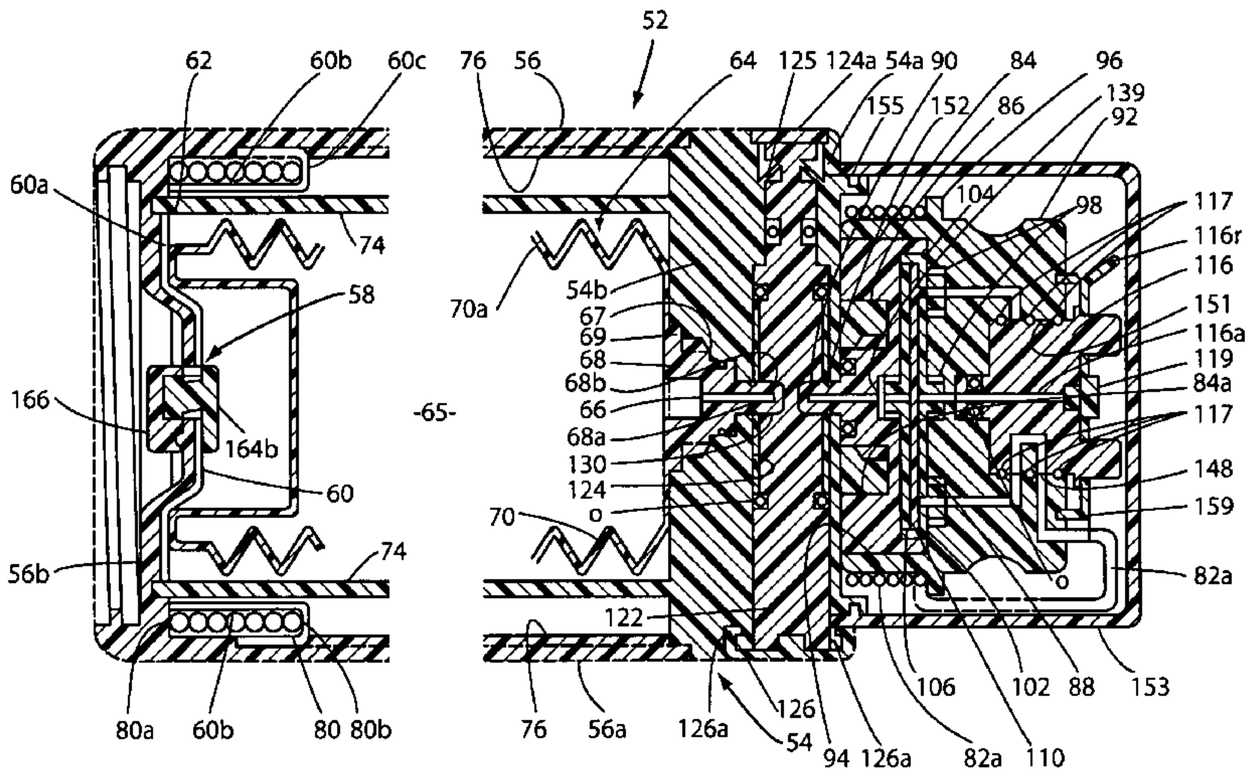
(74) *Attorney, Agent, or Firm* — James E. Brunton

(57) **ABSTRACT**

A compact fluid dispenser for use in controllably dispensing fluid medicaments, such as antibiotics, blood clotting agents, analgesics, and like medicinal agents from collapsible containers at a uniform rate. The dispenser includes a novel stored energy source that is provided in the form of a compressible-expandable member that functions to continuously and uniformly expel fluid from the device reservoir. The apparatus further includes a novel fluid flow control assembly that precisely controls the flow of the medicament solutions from the device reservoir to the patient.

5 Claims, 68 Drawing Sheets



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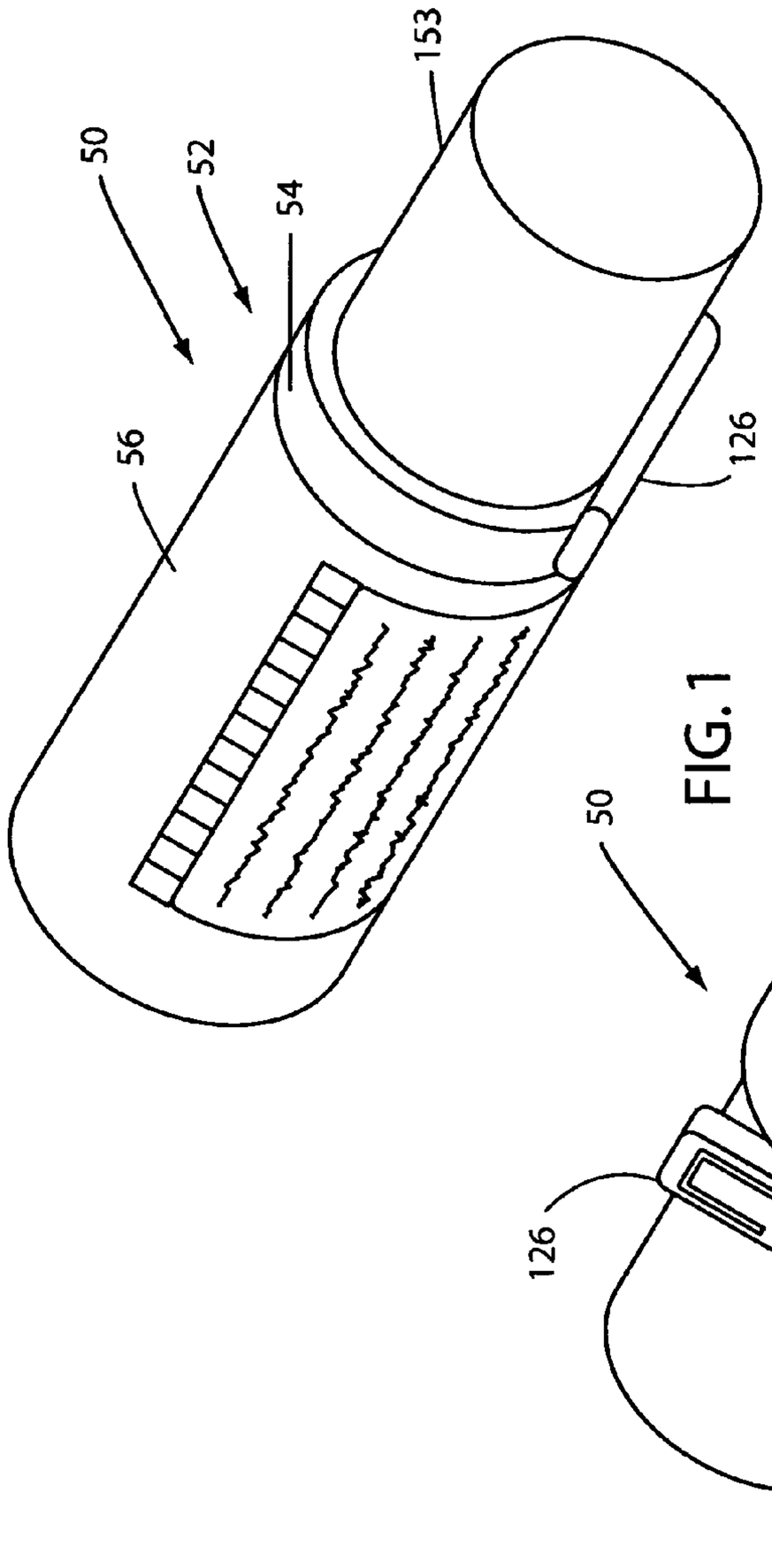

FIG. 1

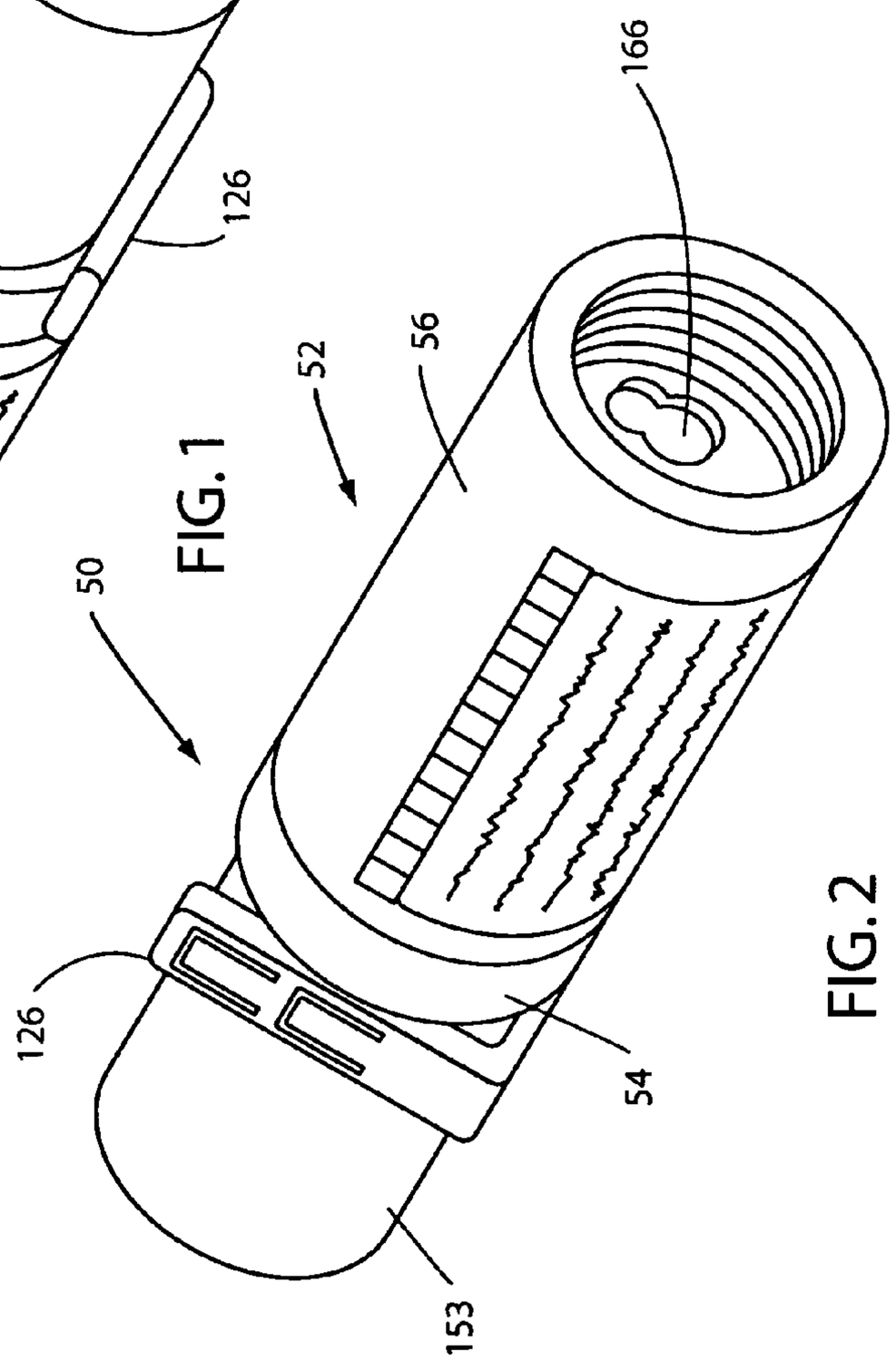

FIG. 2

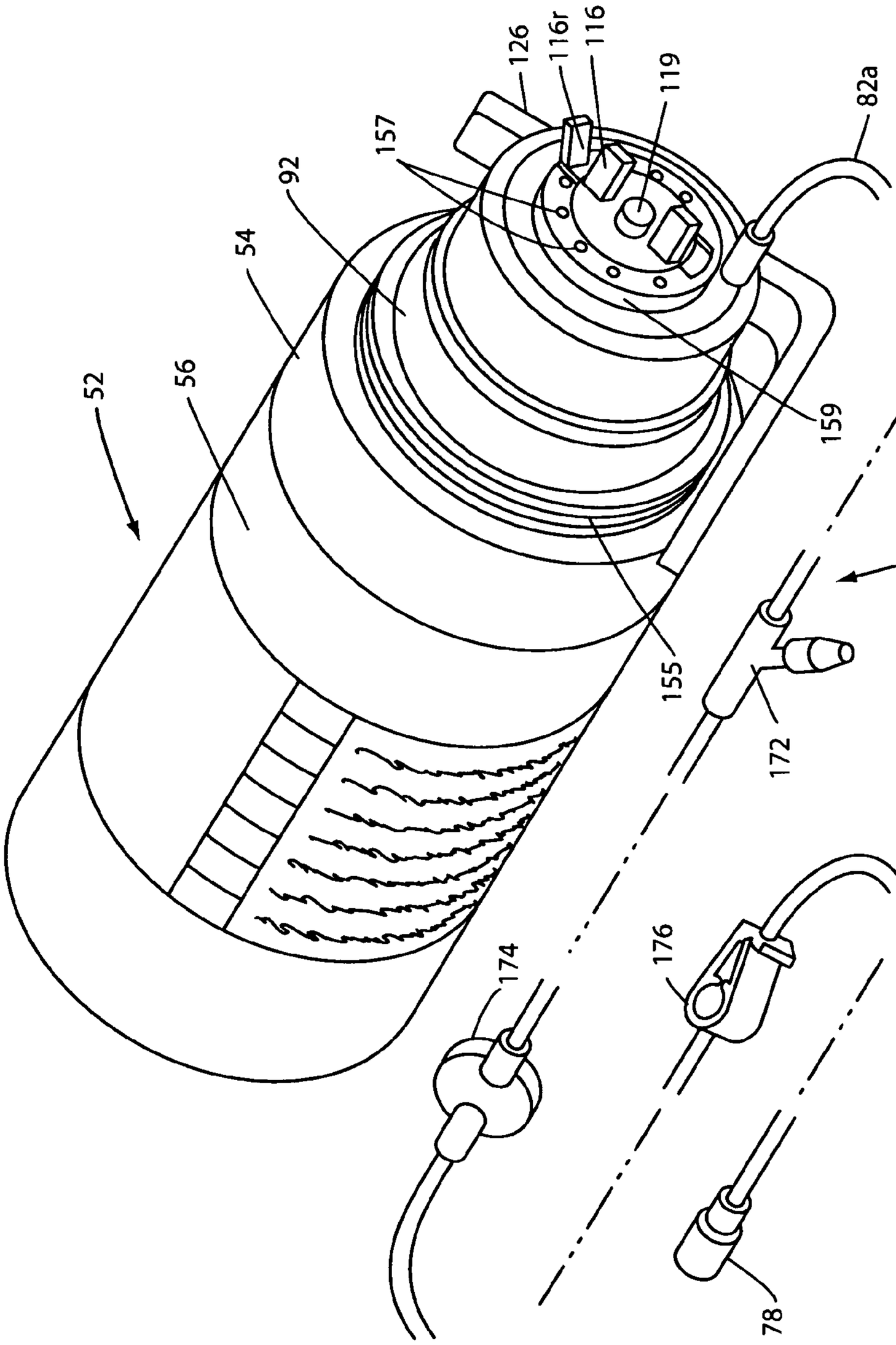

FIG. 3

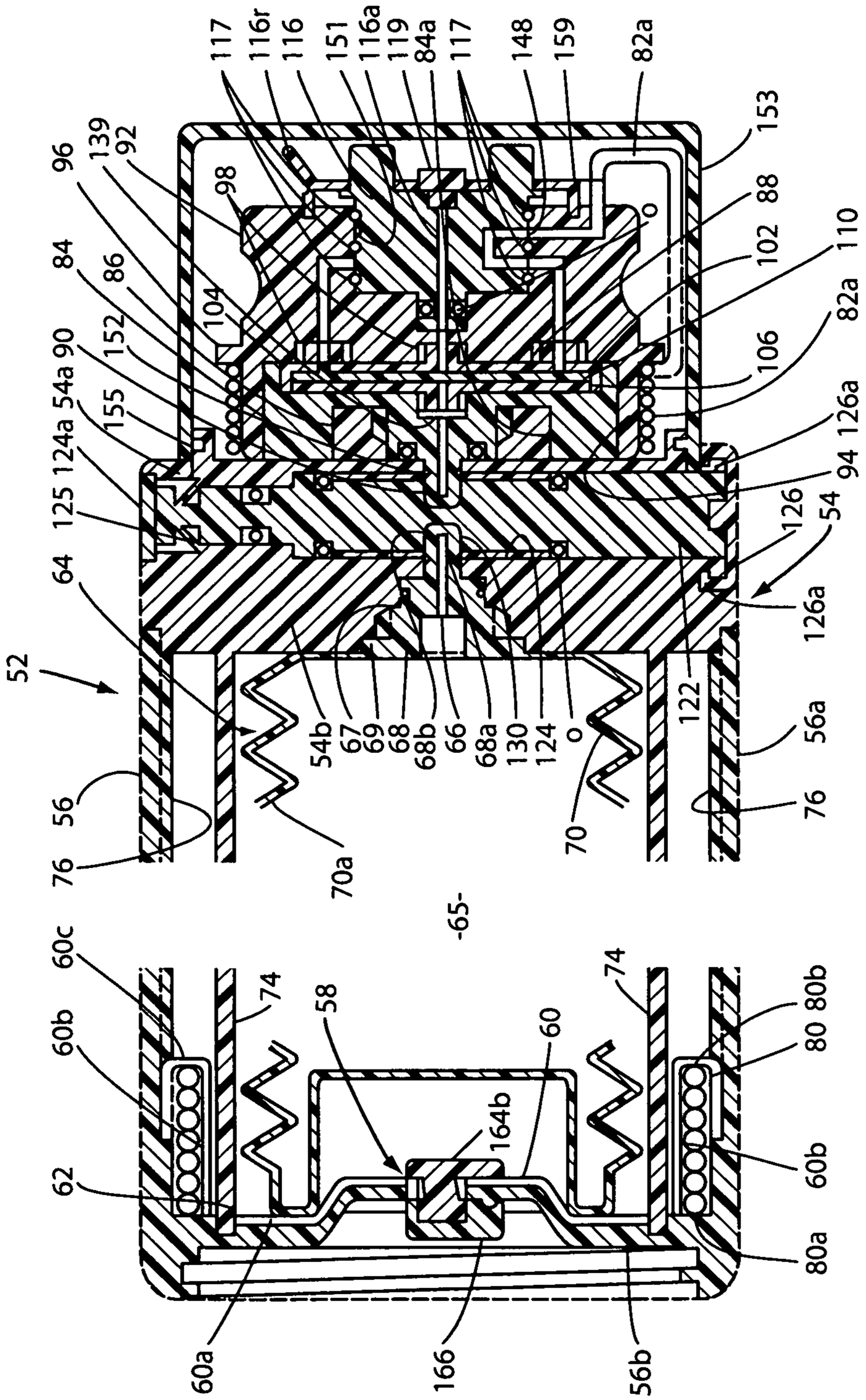
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FIG. 4

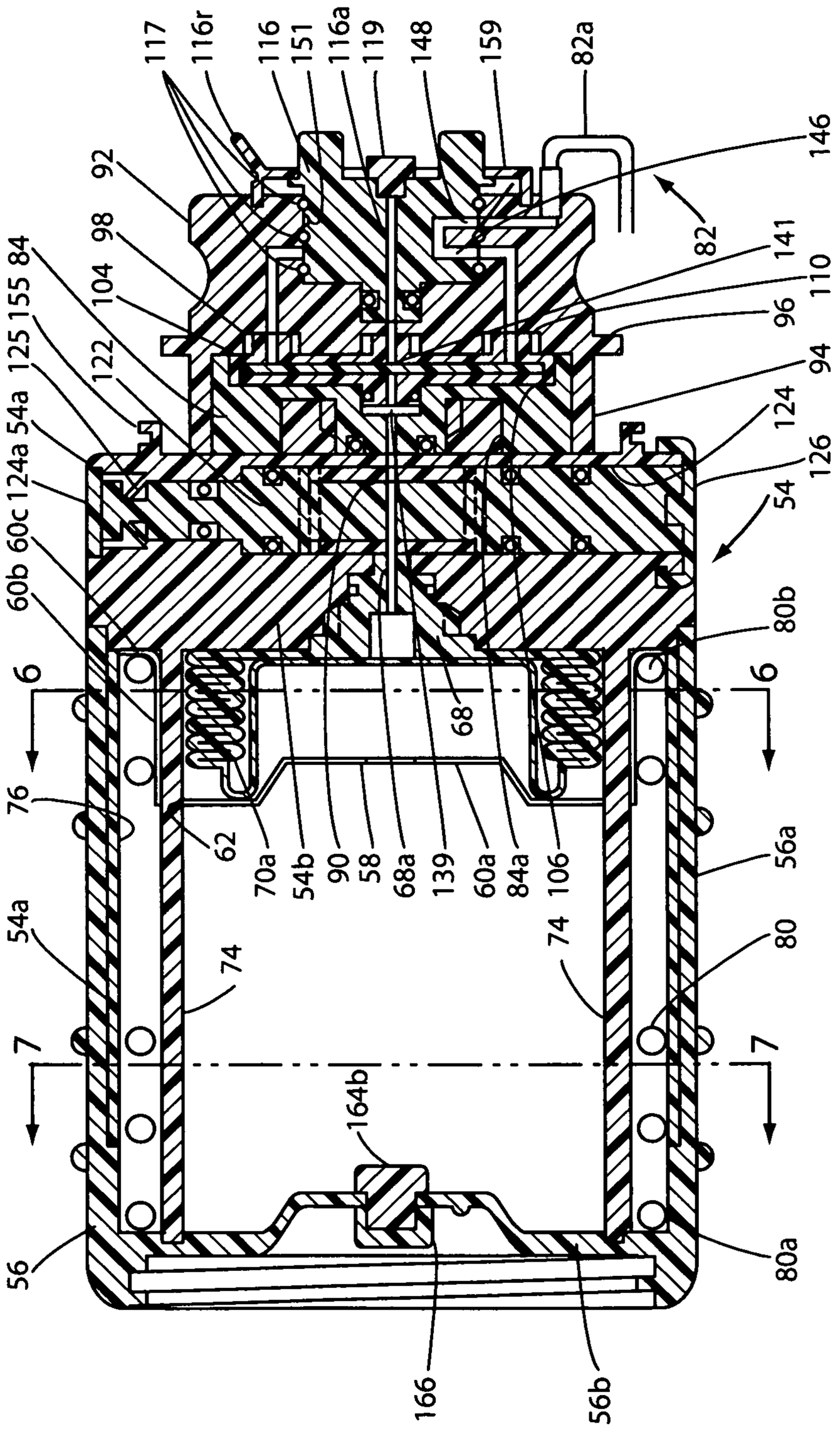
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FIG. 5

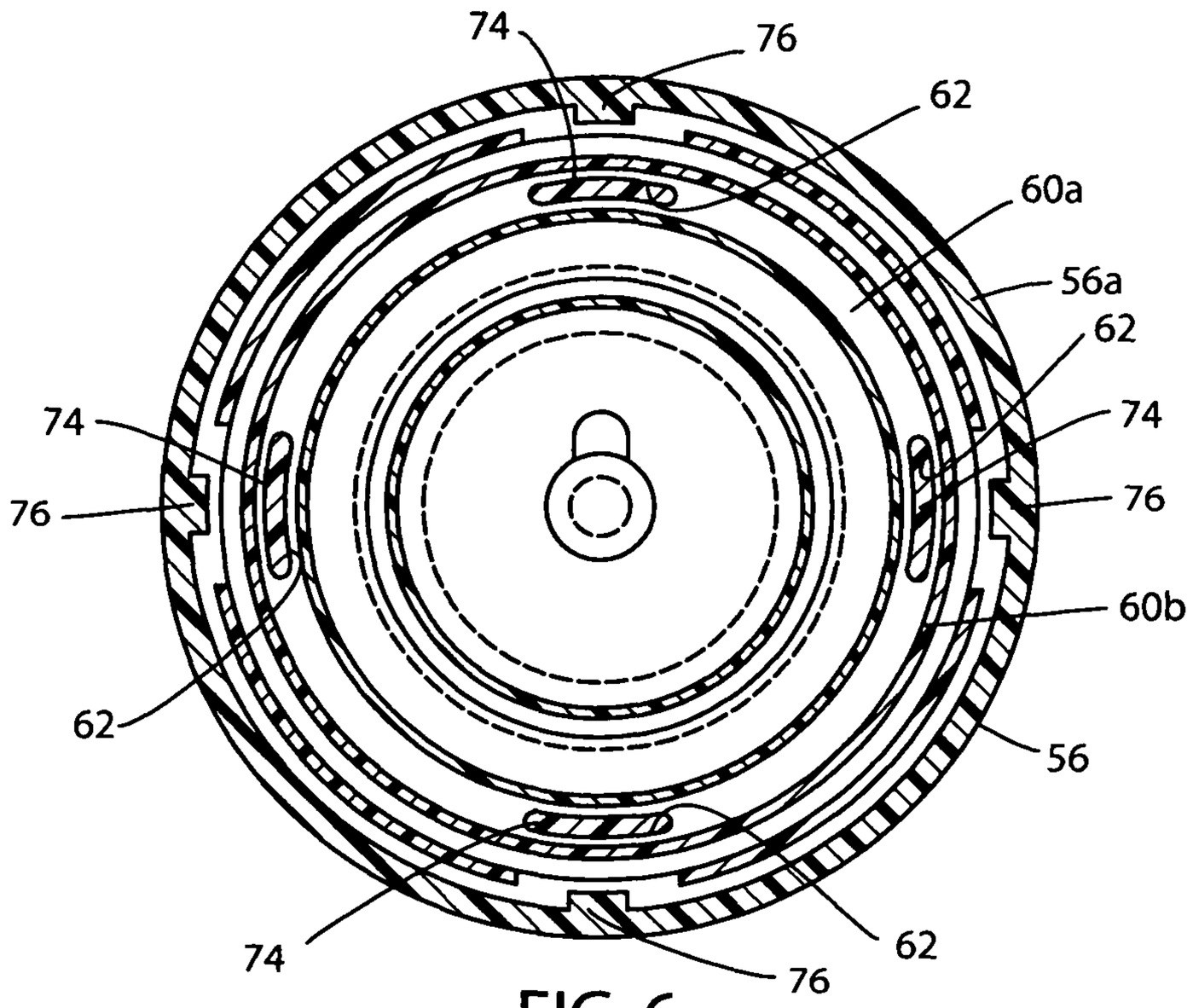
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FIG. 6

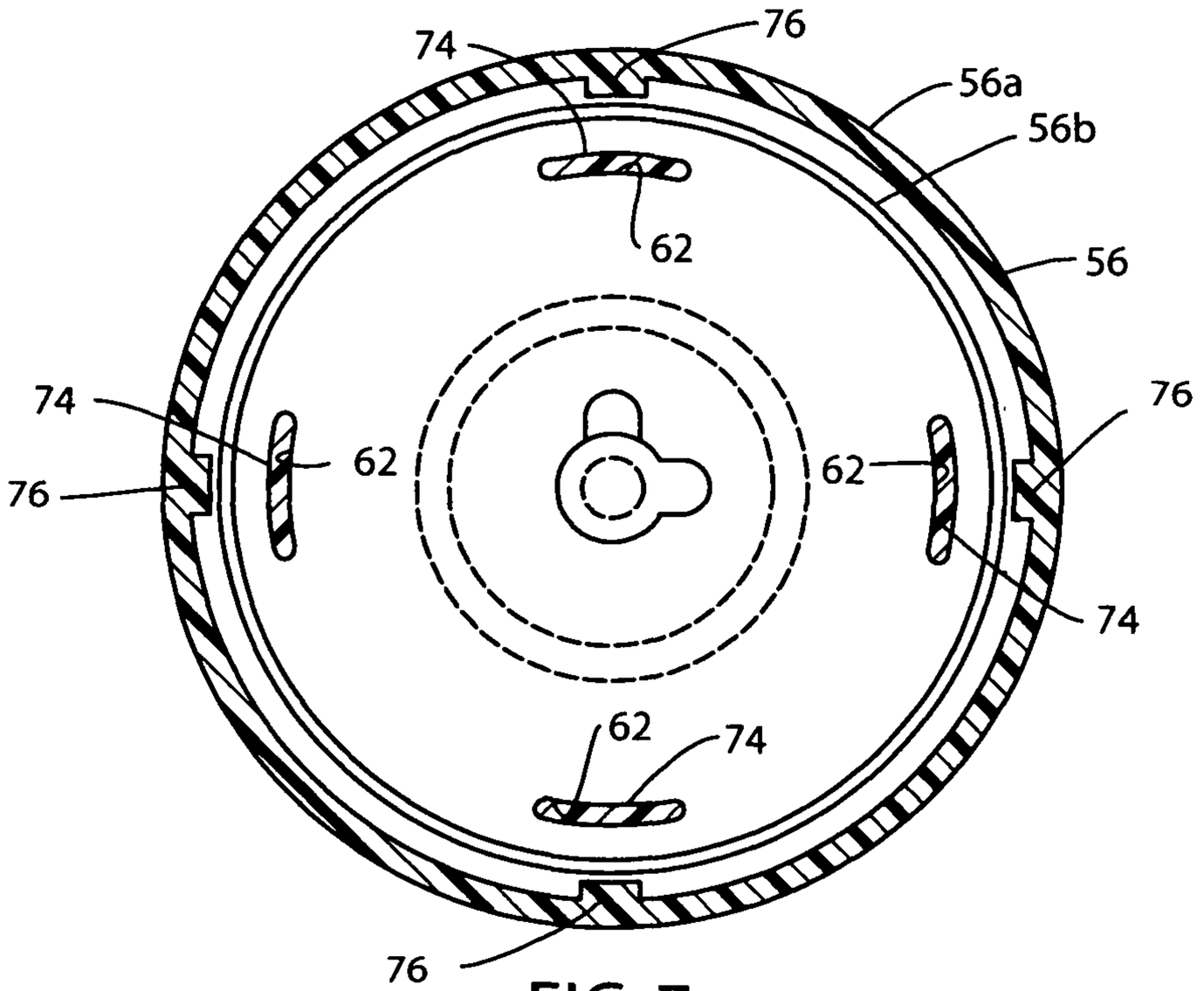
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FIG. 7

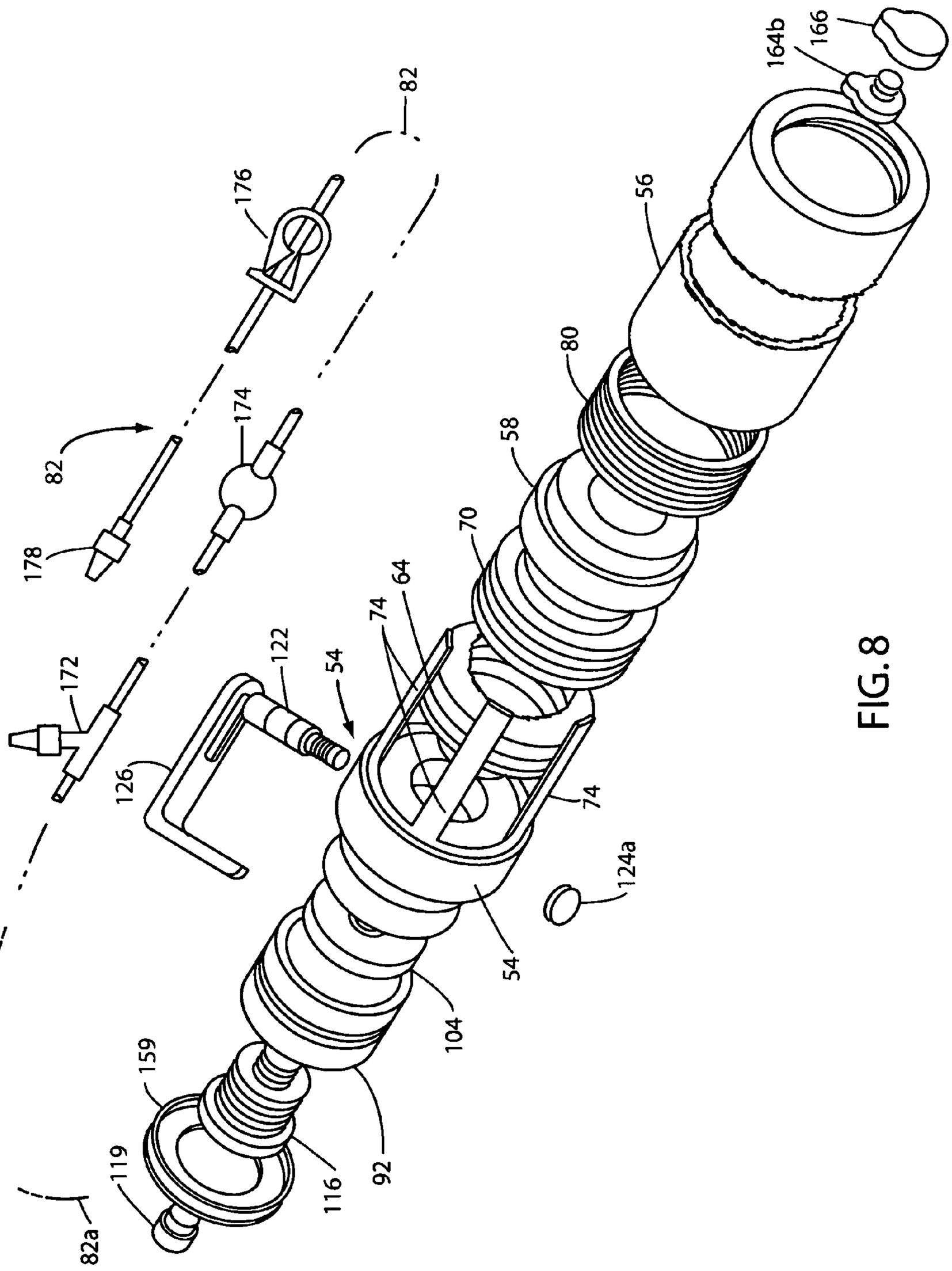
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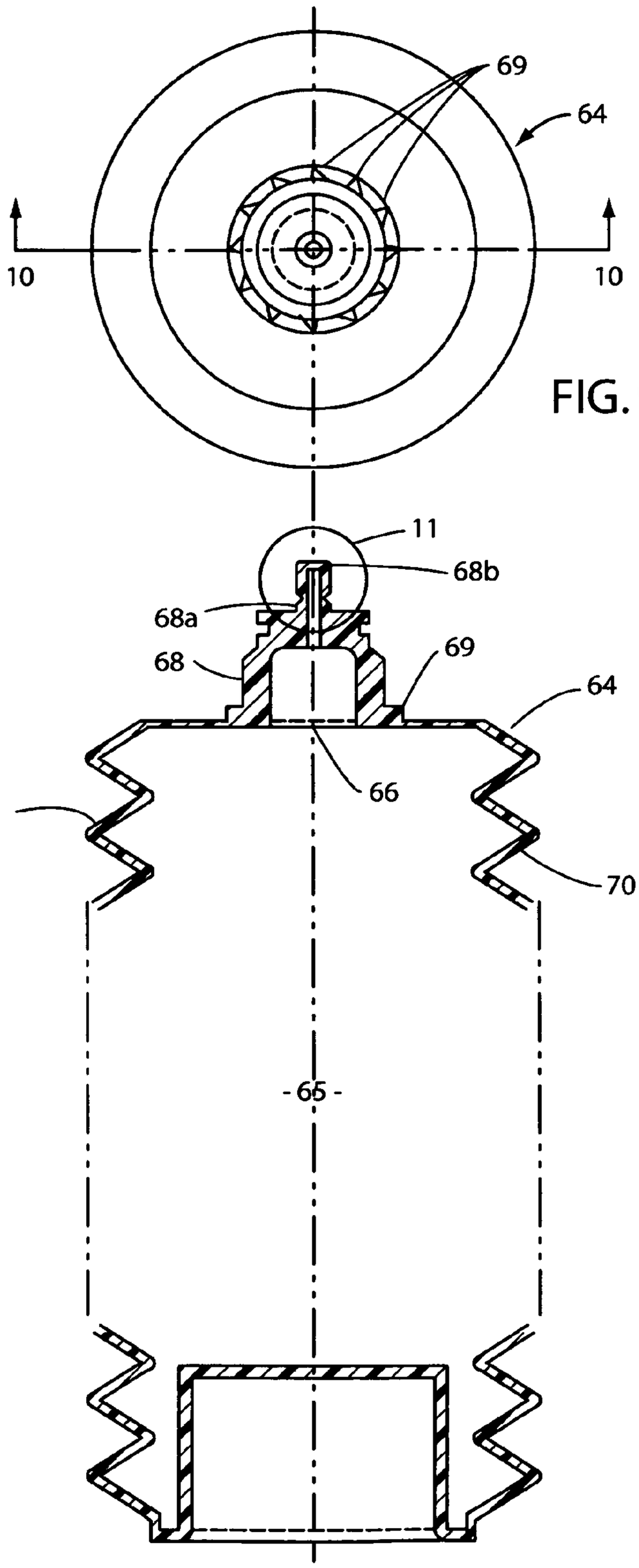
FIG. 8



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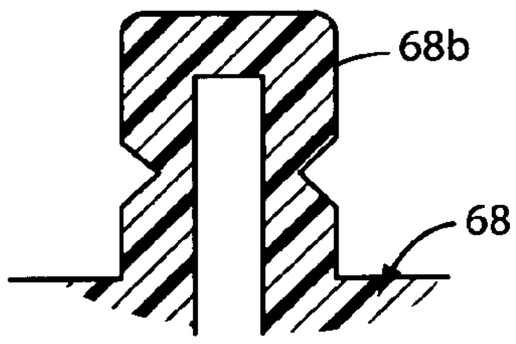


FIG. 11

FIG. 10

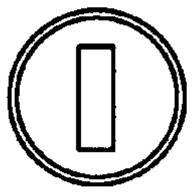
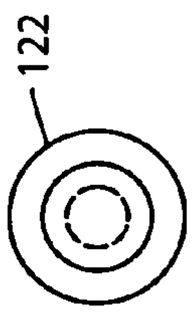


FIG. 14

FIG. 12



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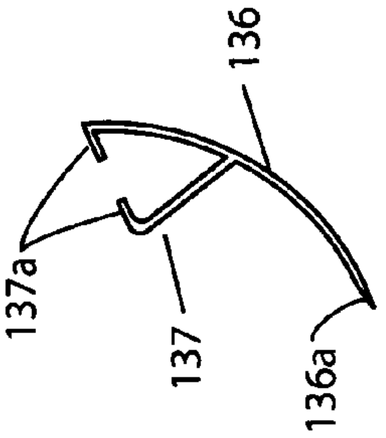

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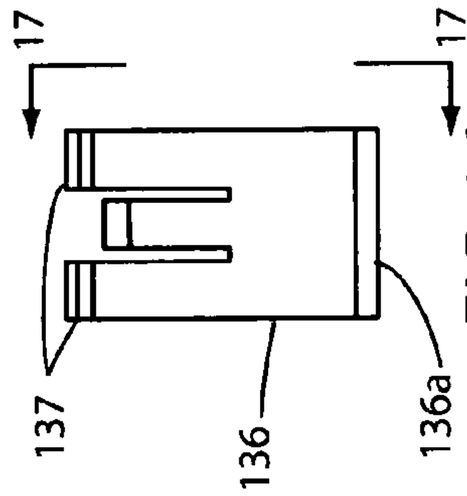

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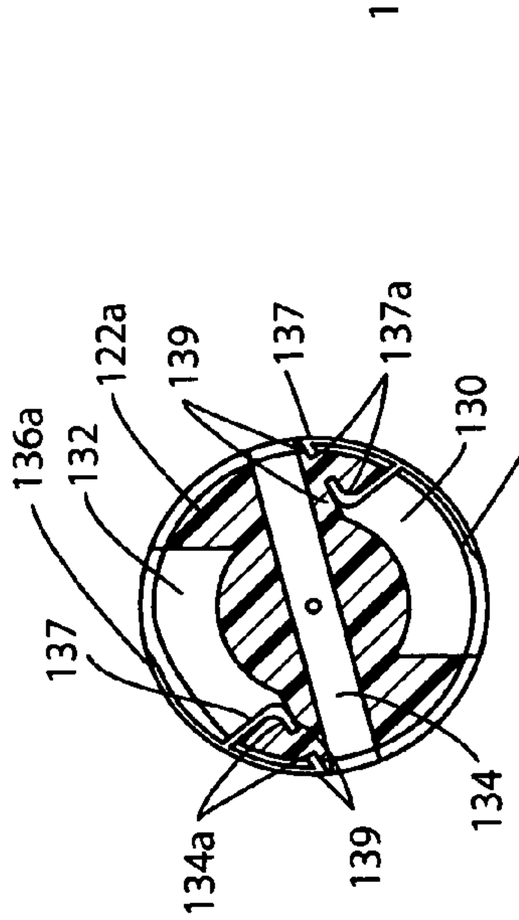

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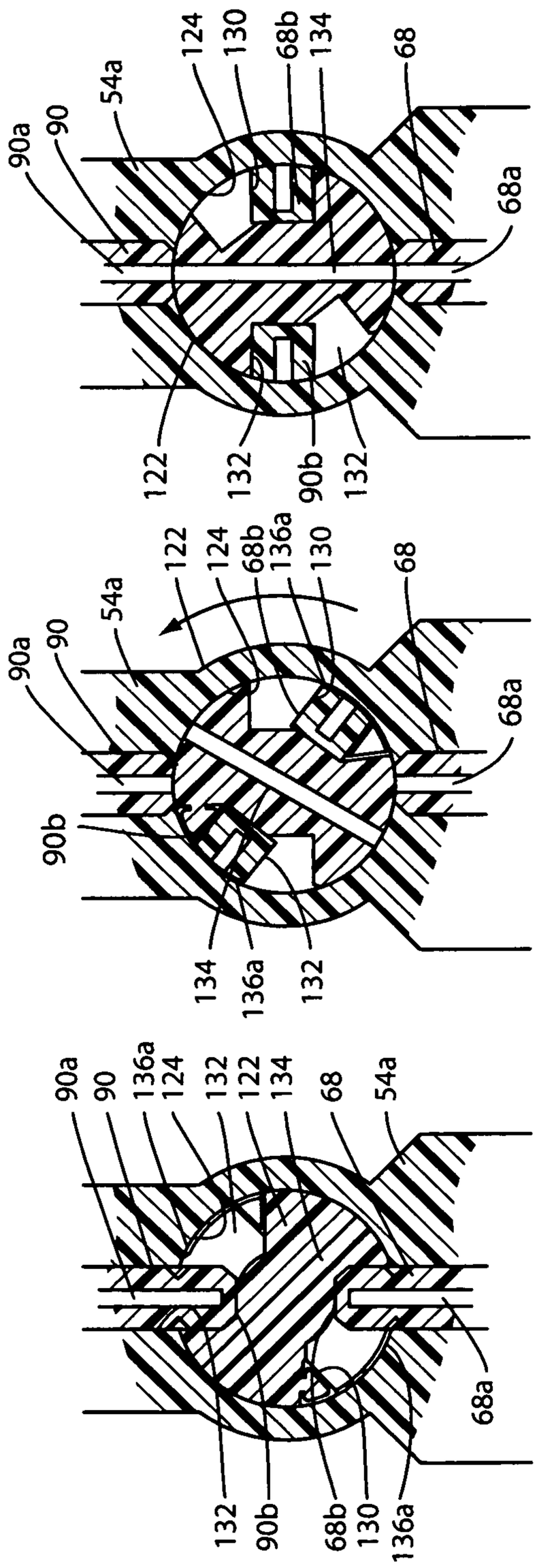


FIG. 20

FIG. 19

FIG. 18

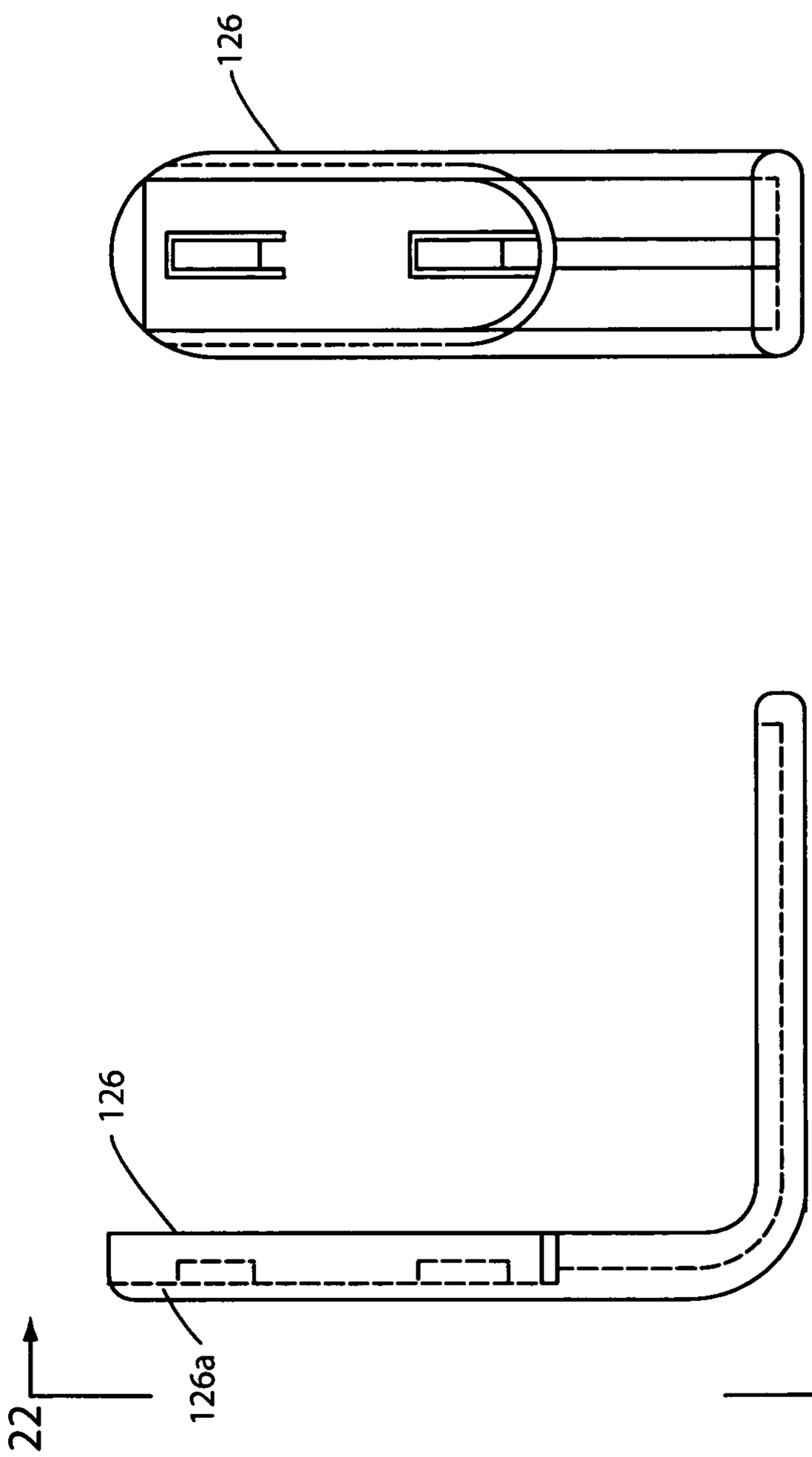


FIG. 21

FIG. 22

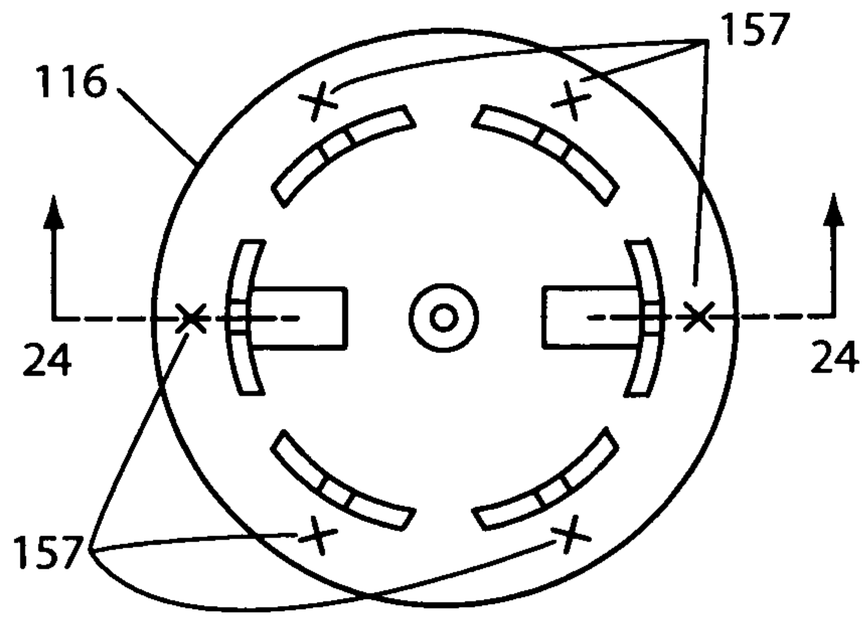
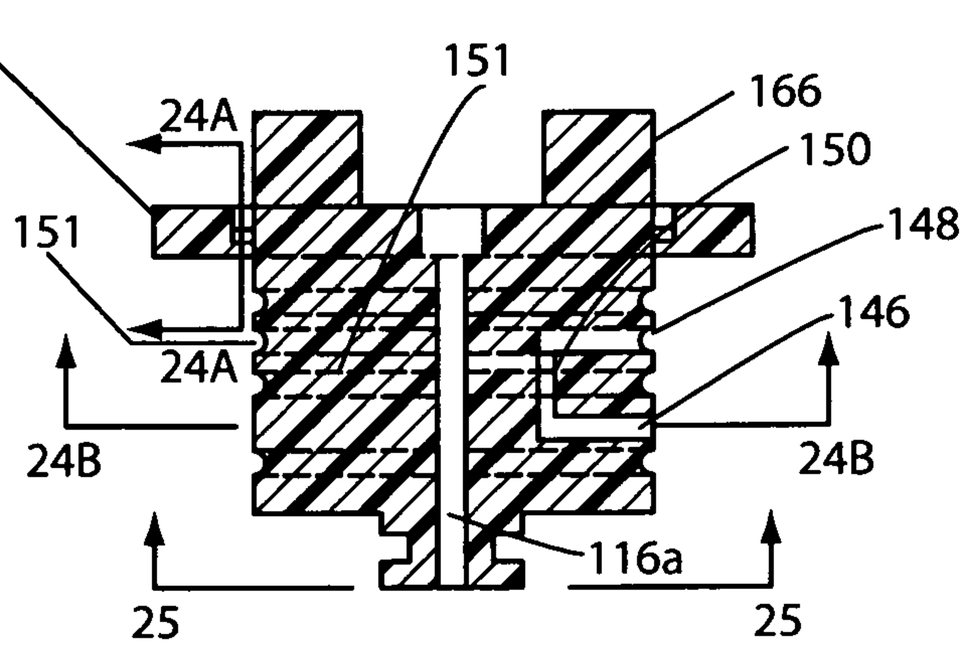


FIG. 23

FIG. 24A



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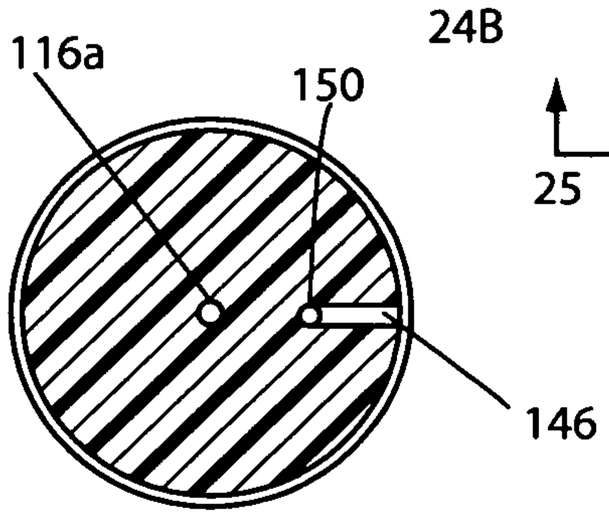

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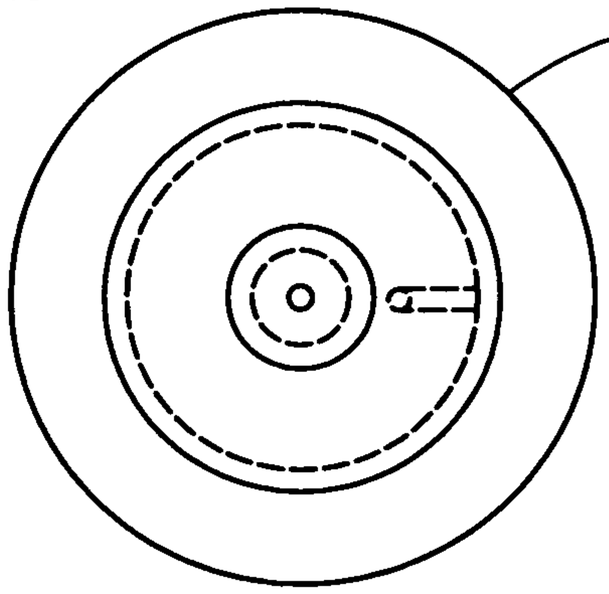

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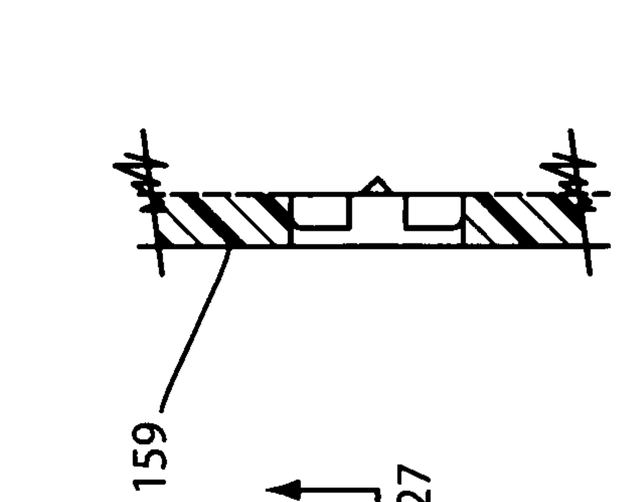

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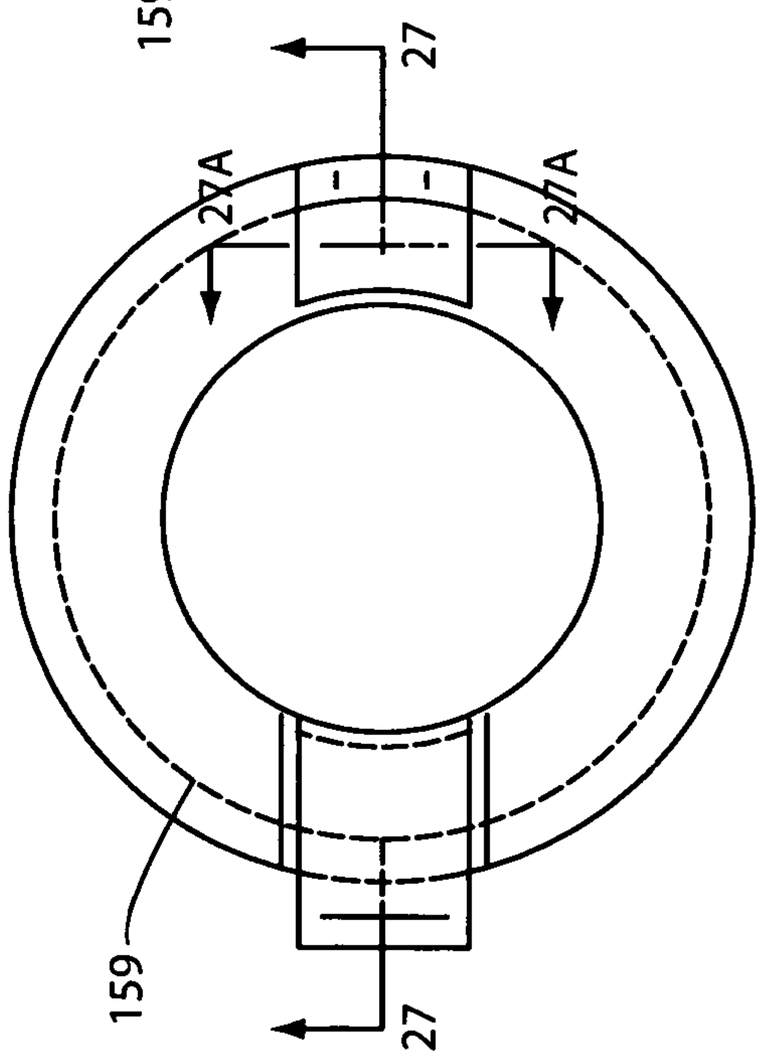

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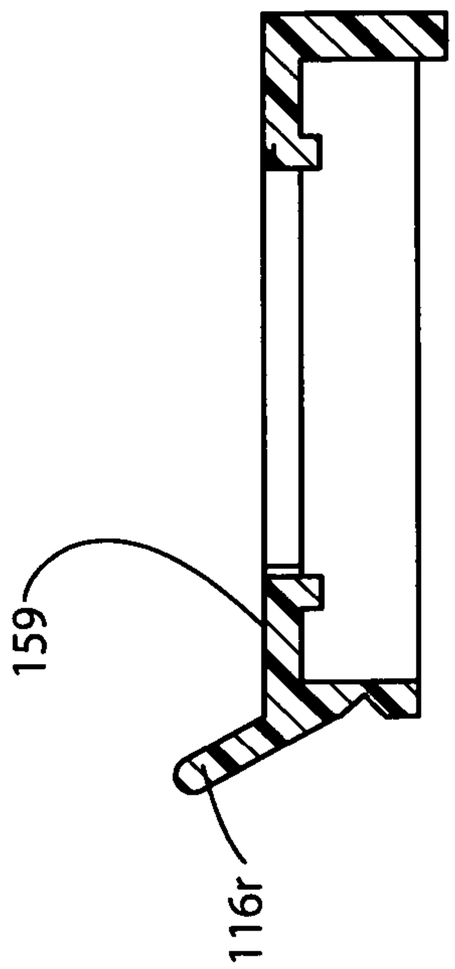

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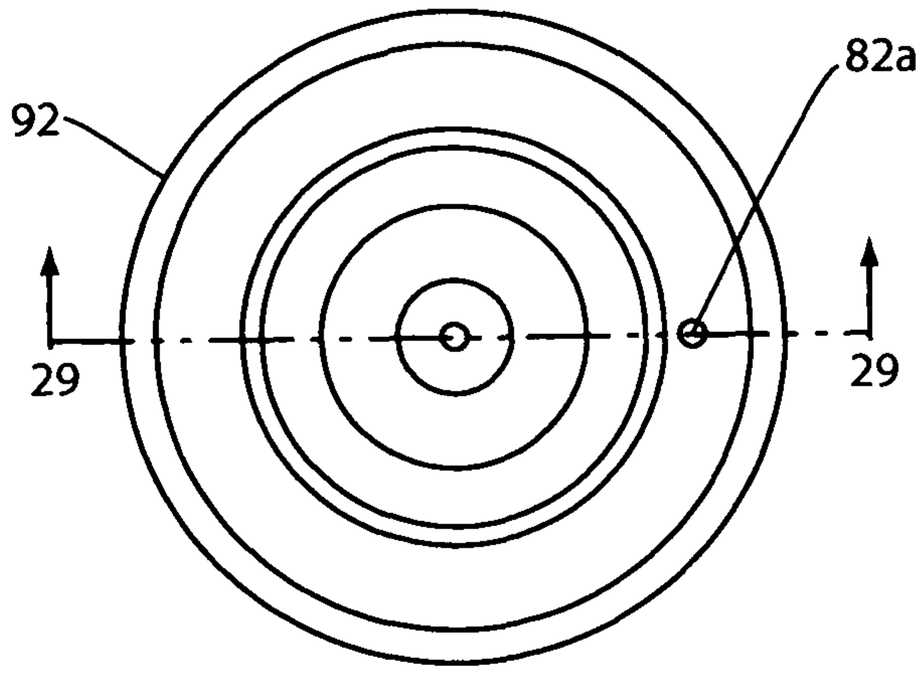

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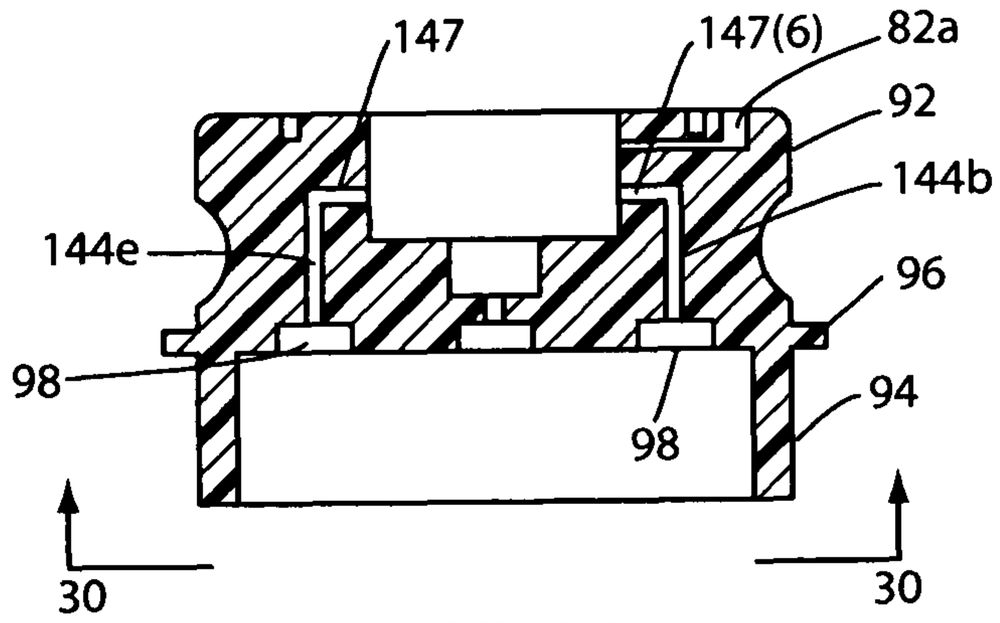

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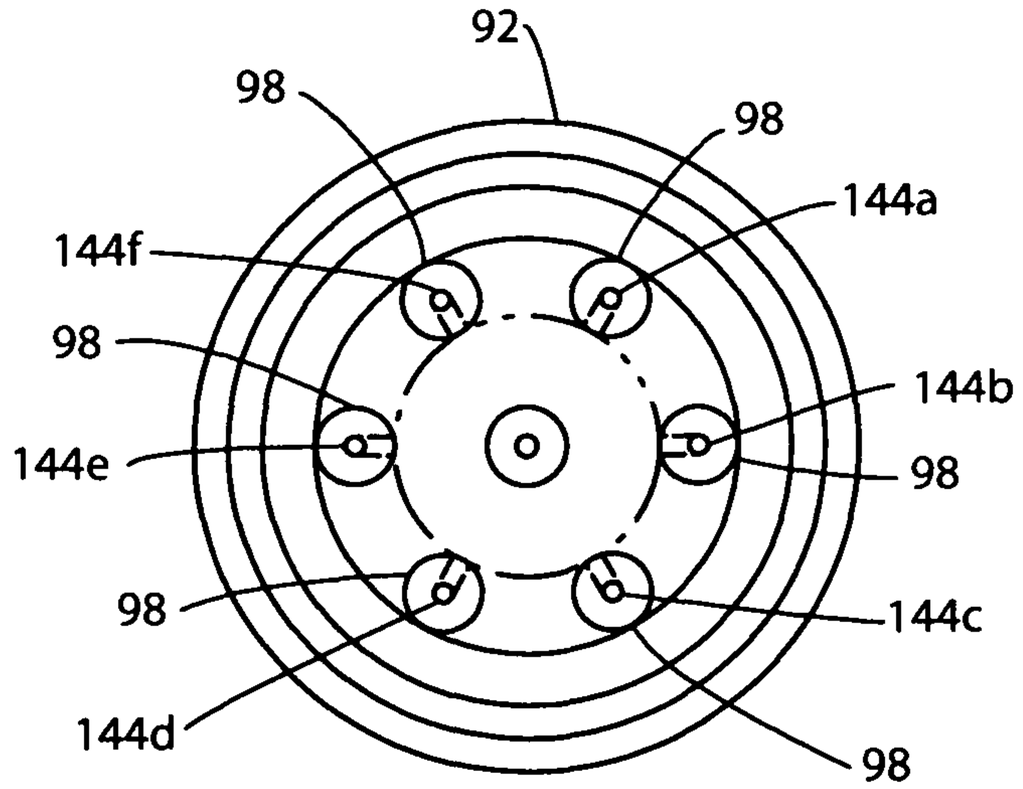
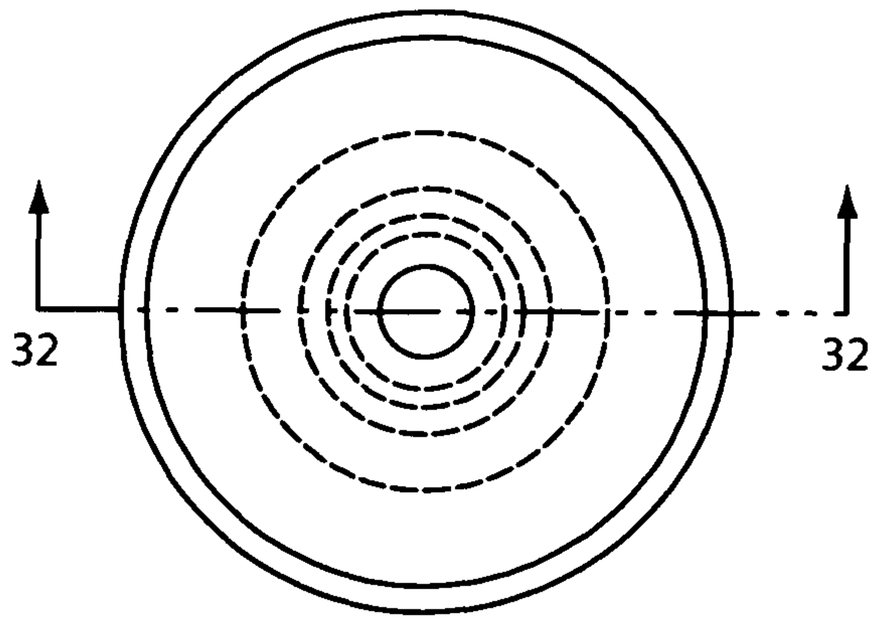


FIG. 30



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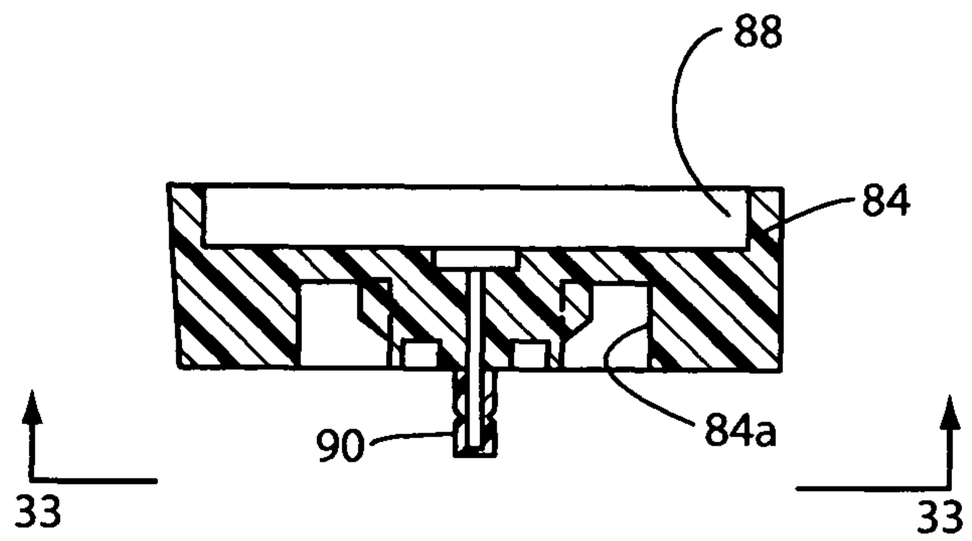


FIG. 32

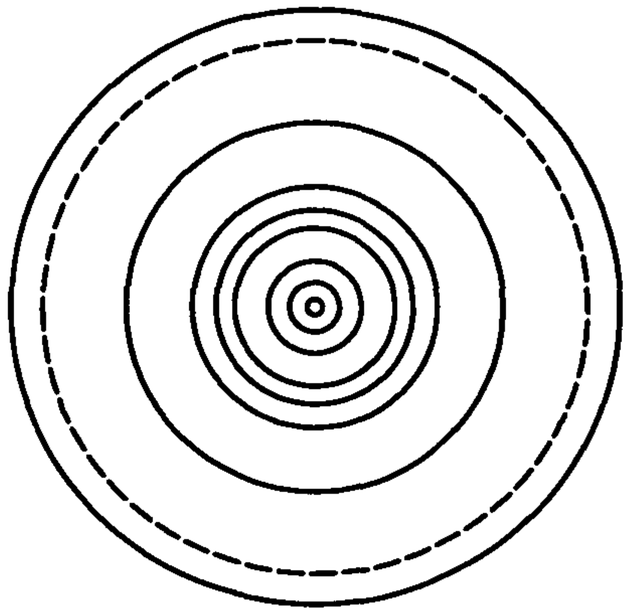


FIG. 33

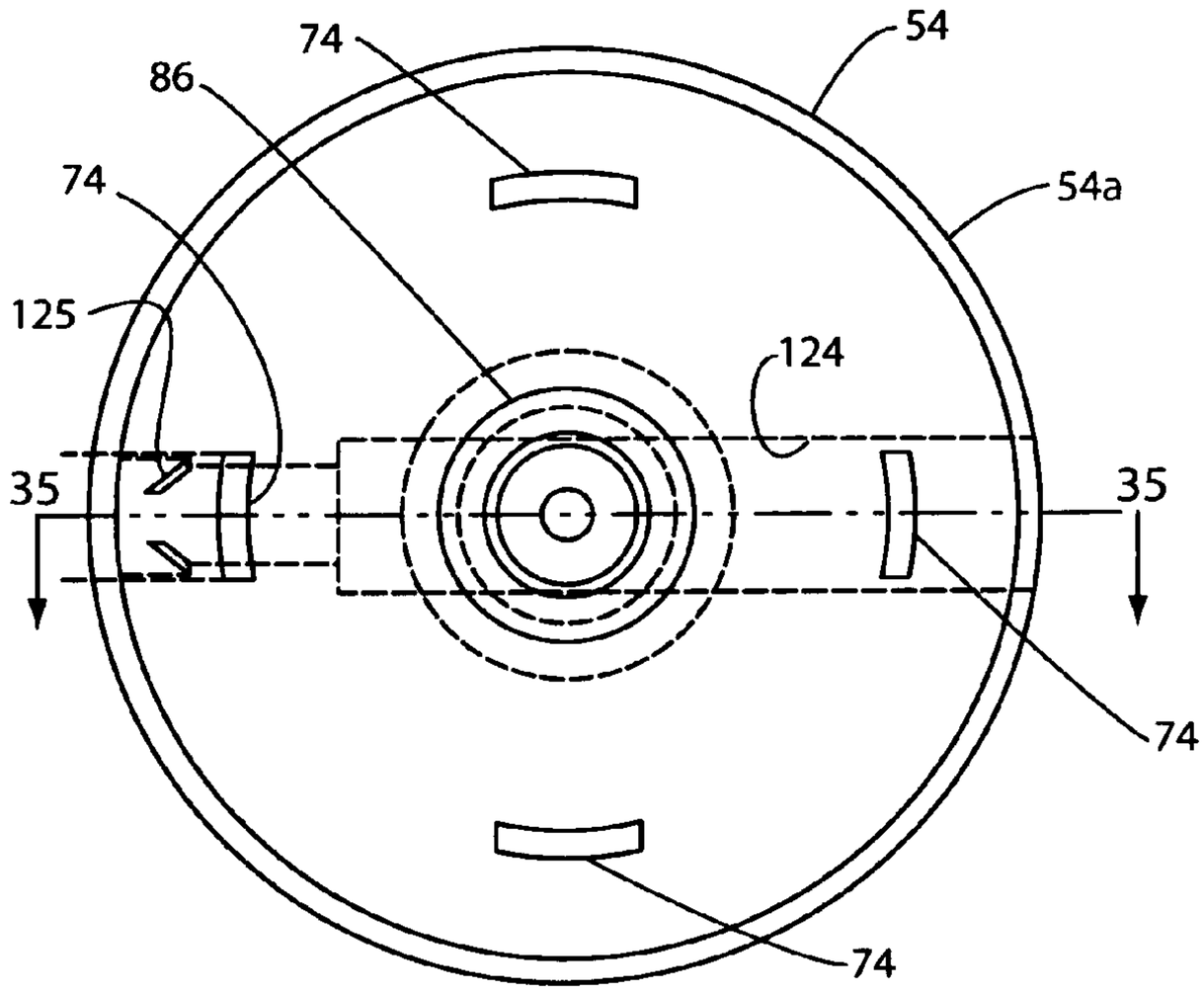


FIG. 34

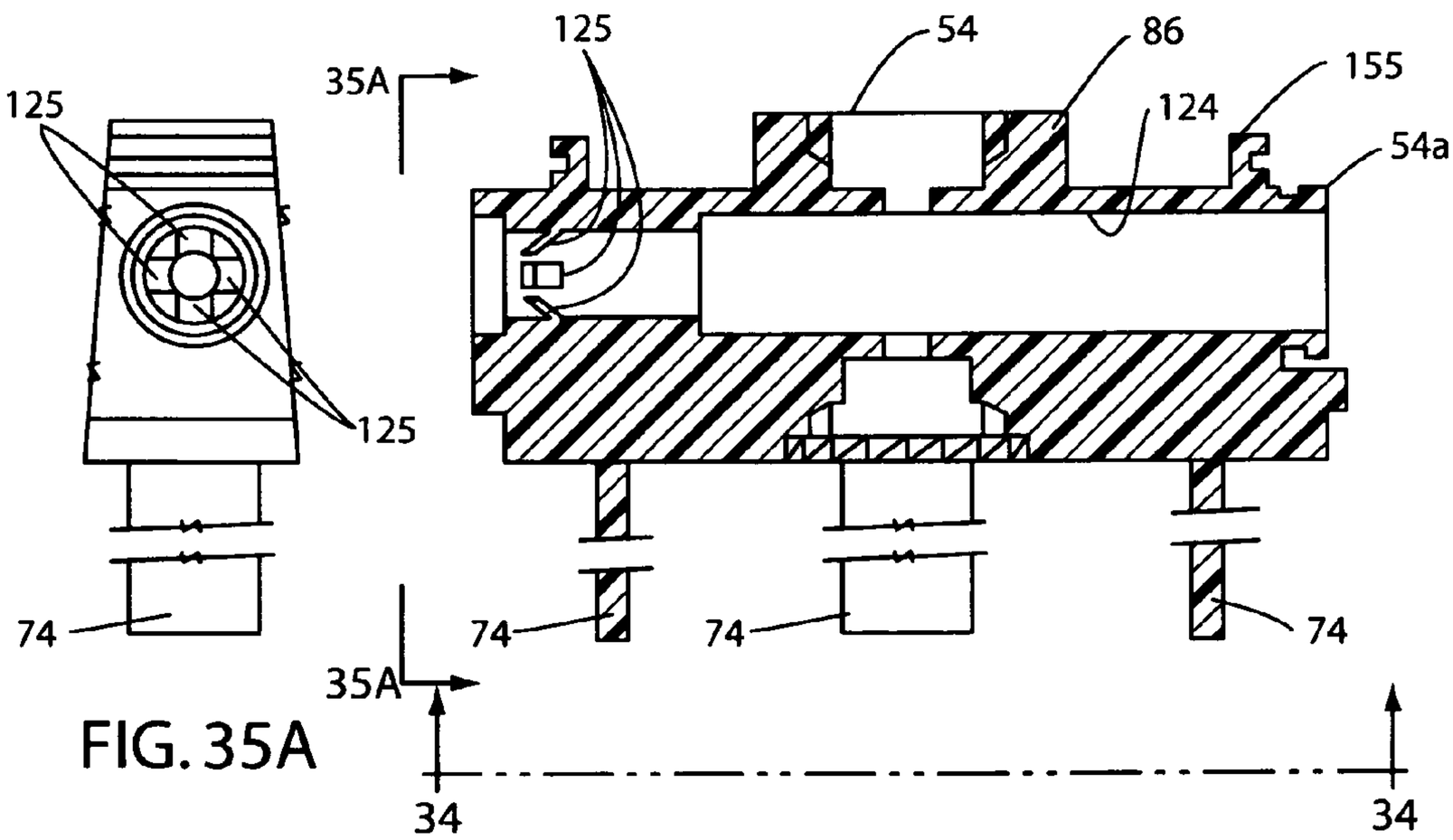


FIG. 35A

FIG. 35

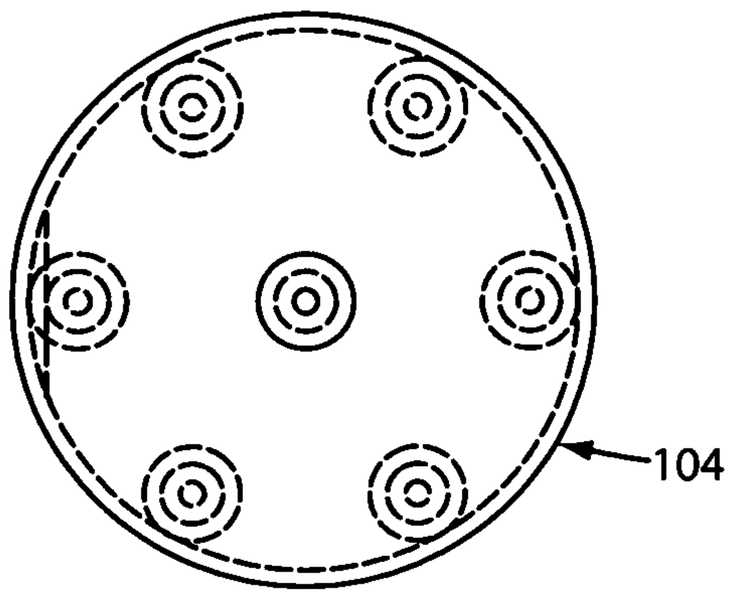


FIG. 38

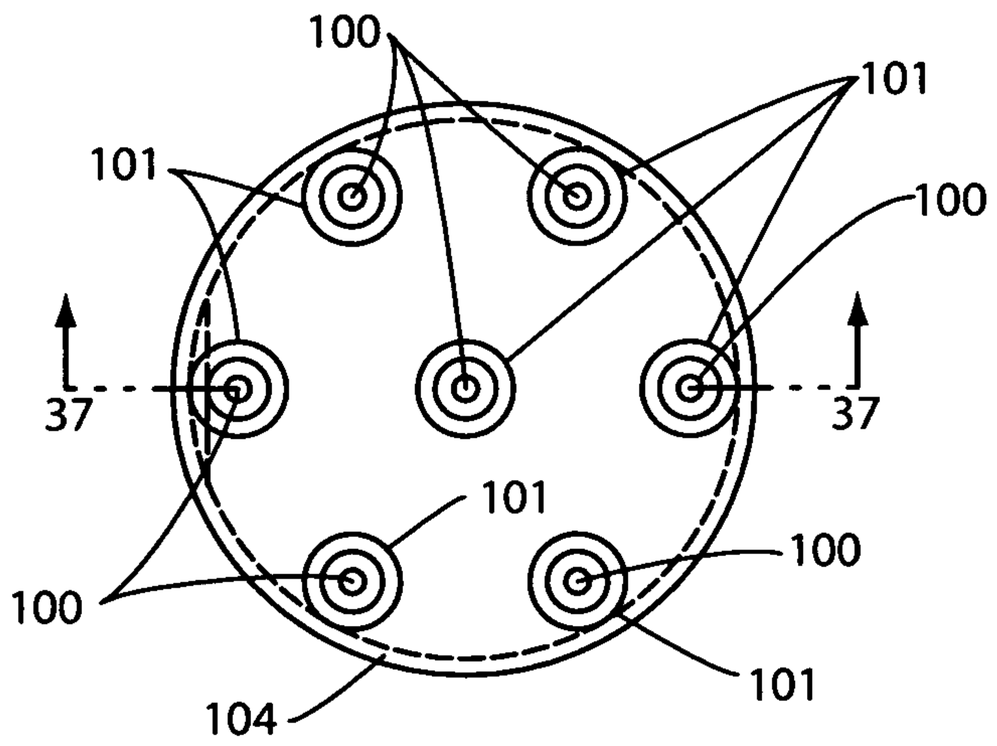


FIG. 36

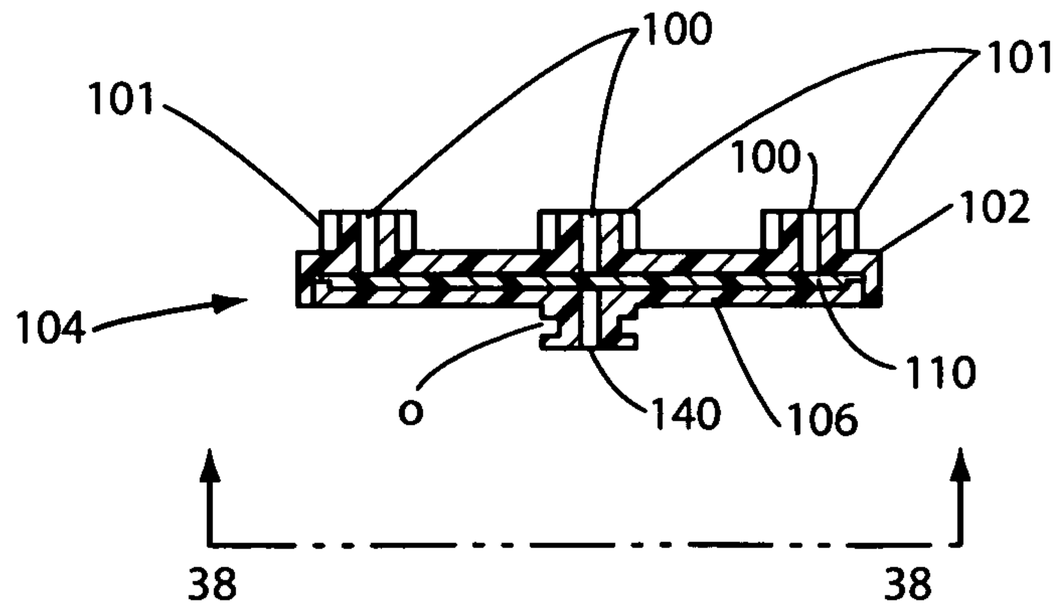


FIG. 37

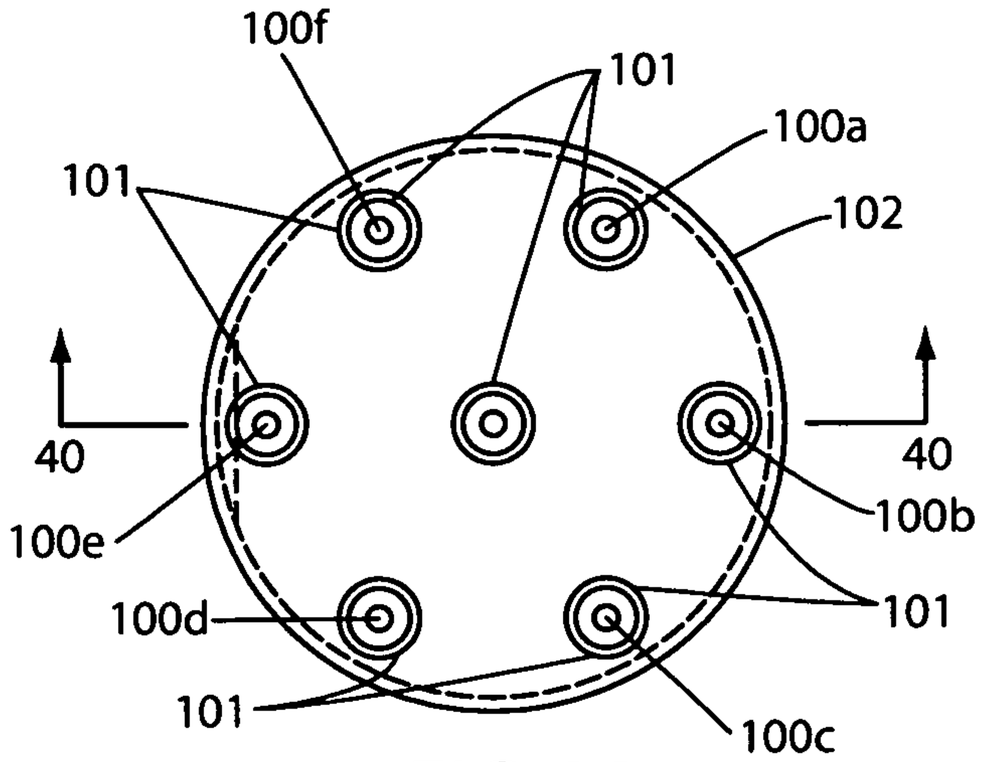


FIG. 39

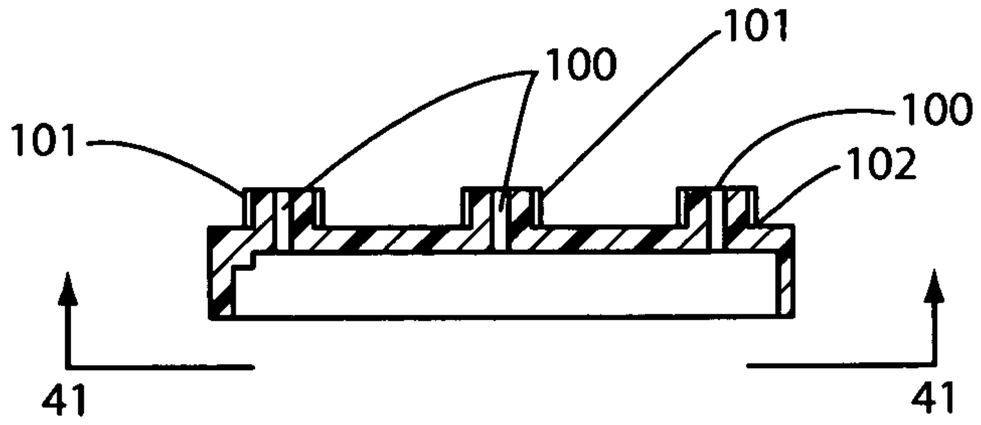


FIG. 40

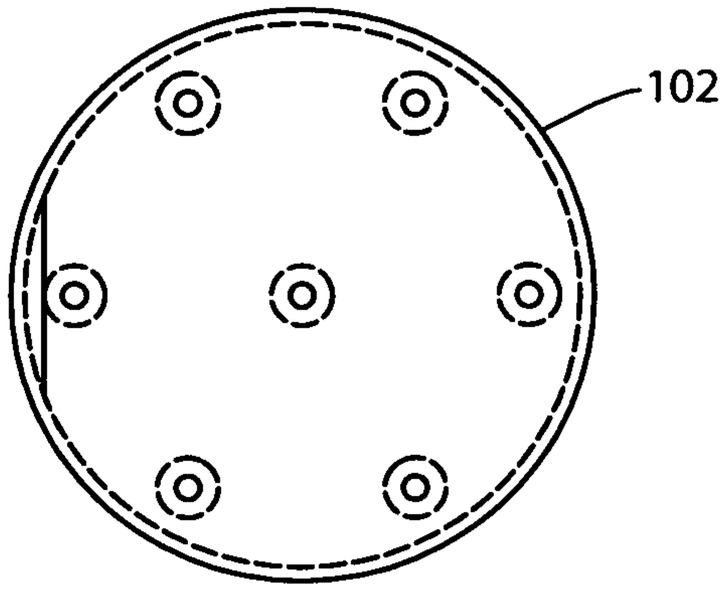


FIG. 41

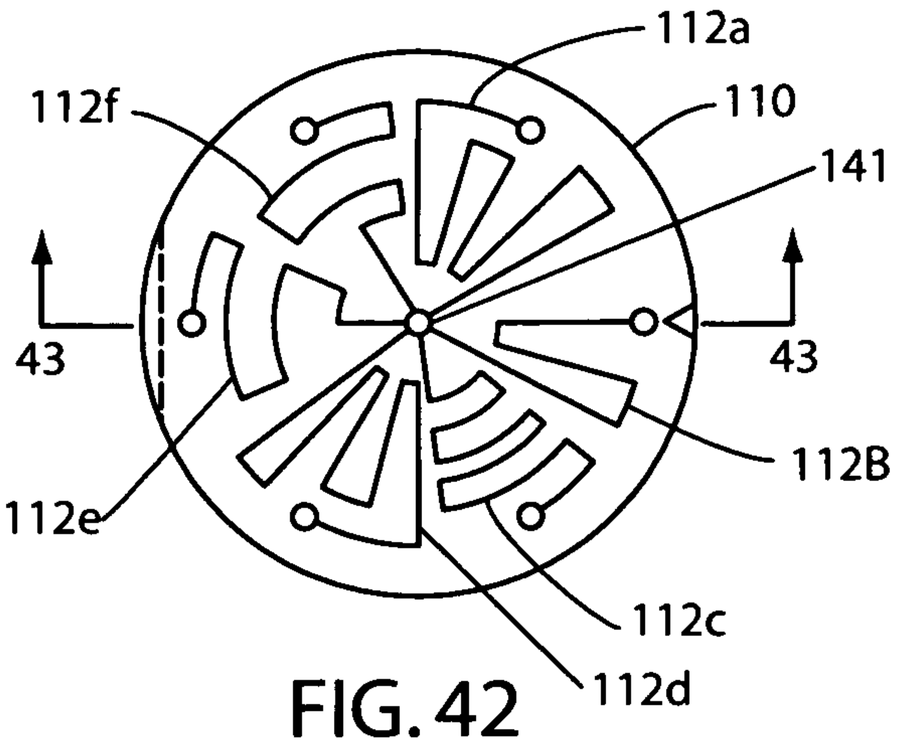


FIG. 42

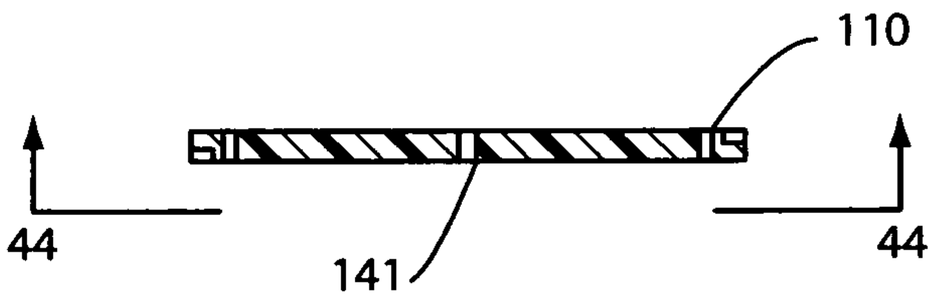


FIG. 43

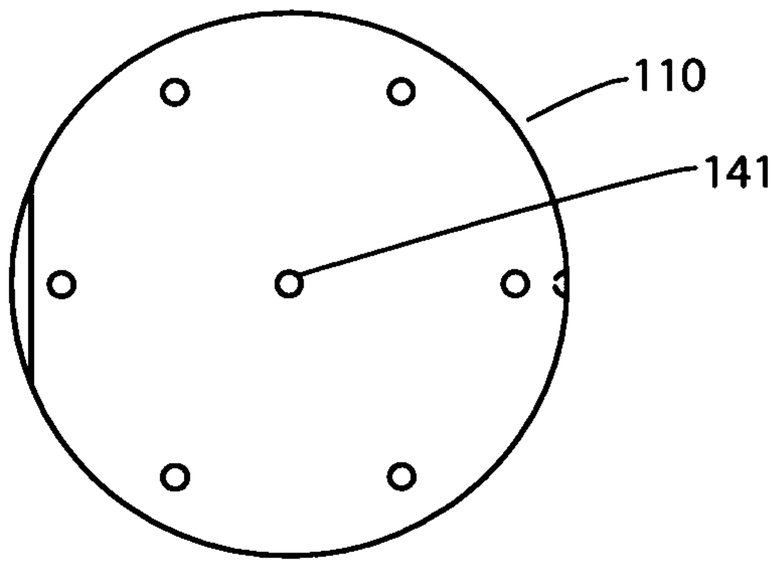


FIG. 44

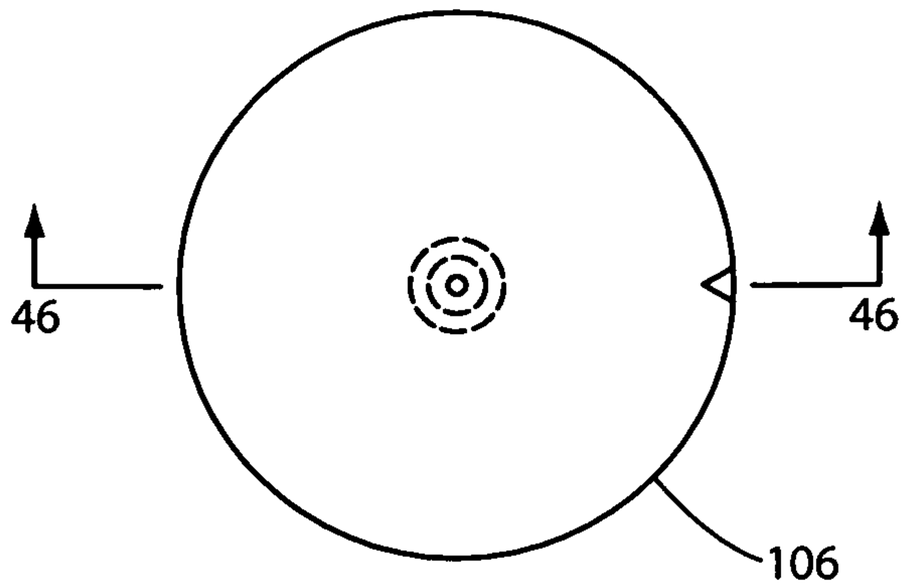


FIG. 45

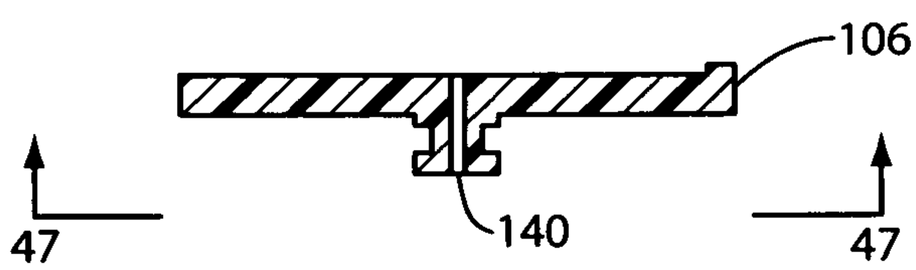


FIG. 46

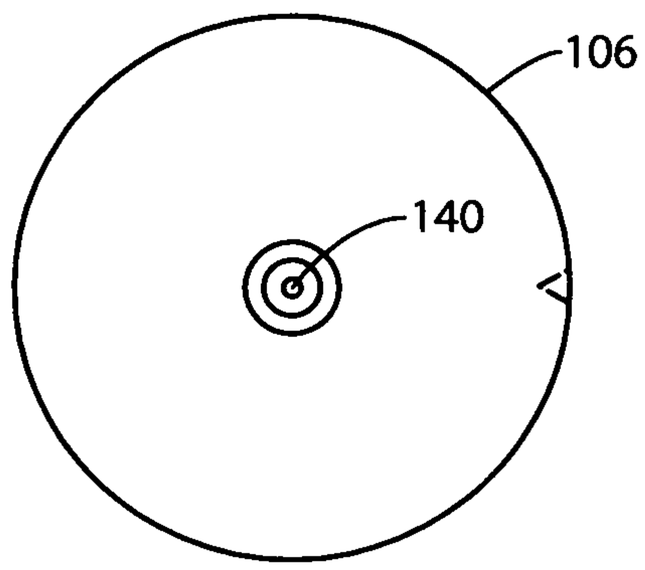
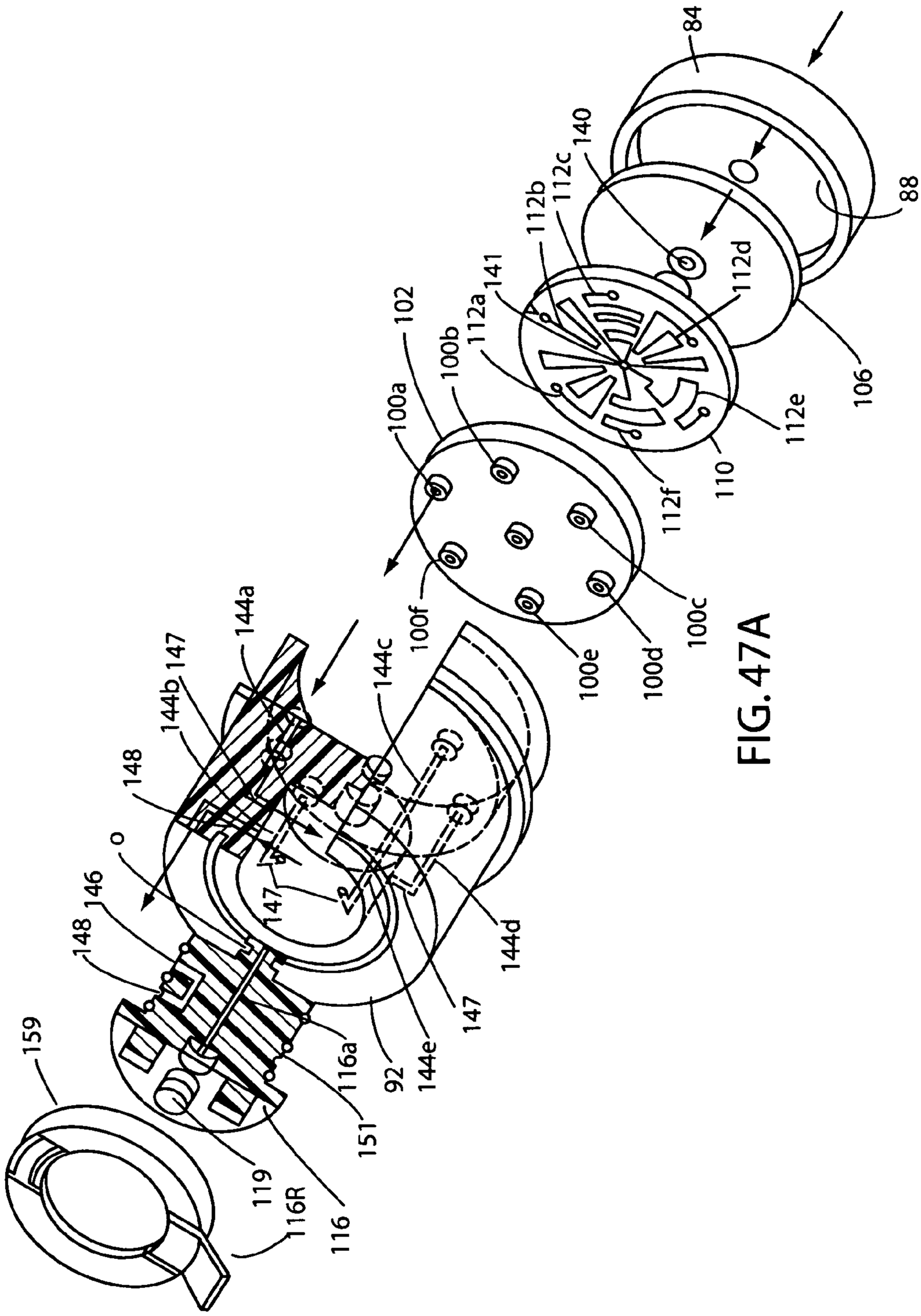


FIG. 47


84
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112d
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112a
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100b
100a
100f
100e
100d
100c
112f
110
112e
106
144a
144b
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144c
148
146
144d
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159
119
116R
116
151
116a
92
144e
147

FIG. 47A

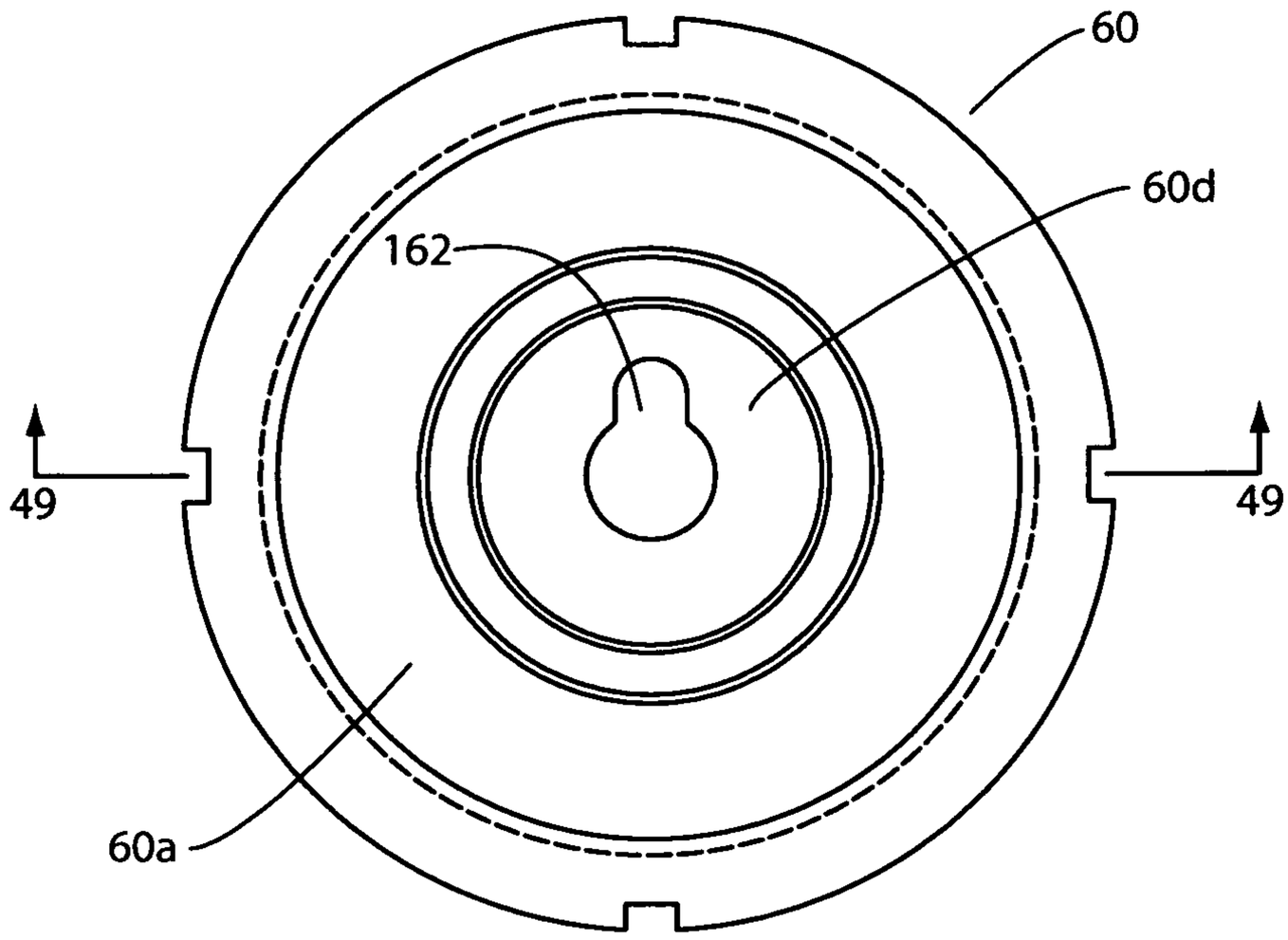


FIG. 48

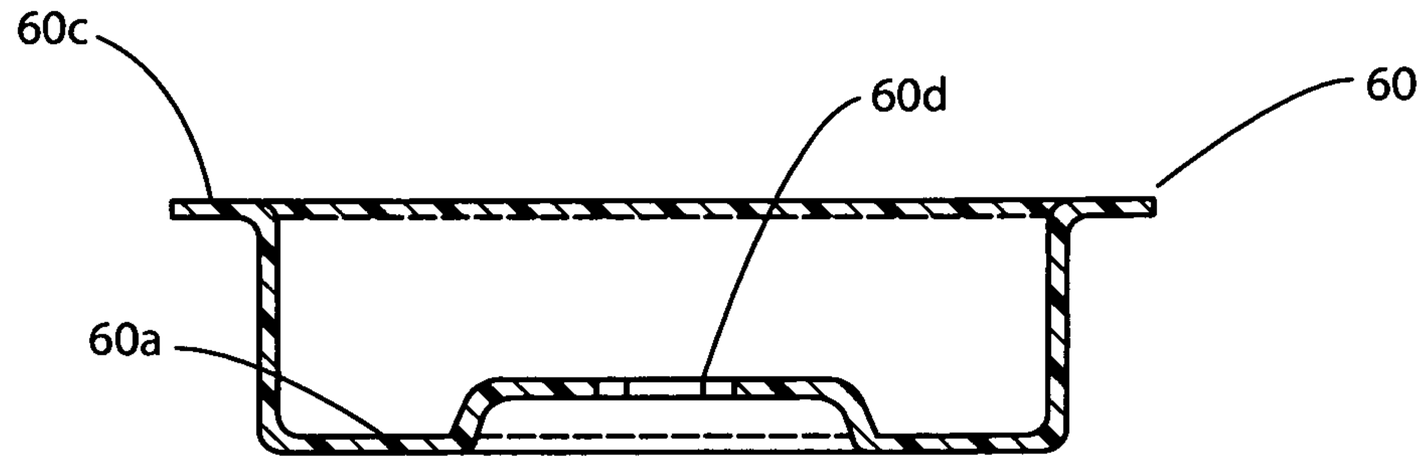


FIG. 49

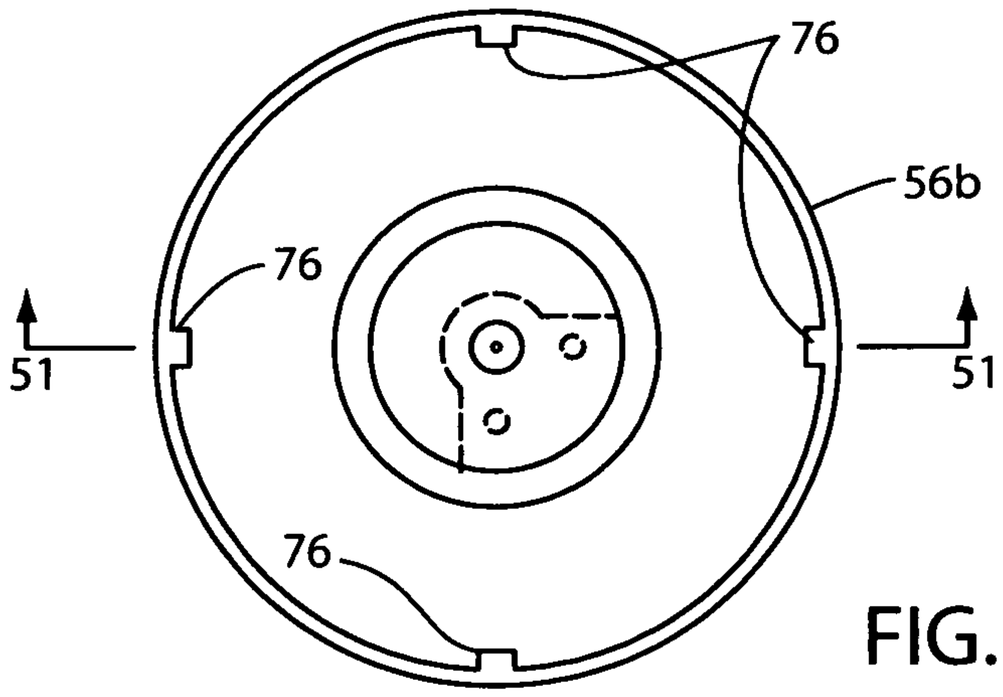


FIG. 50

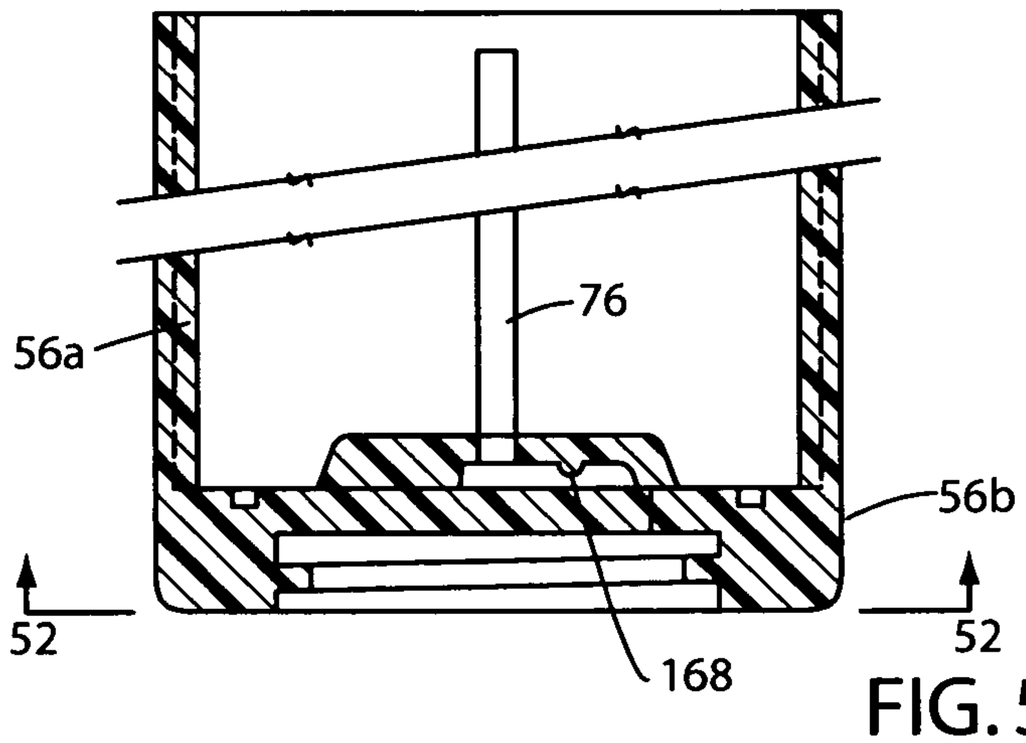


FIG. 51

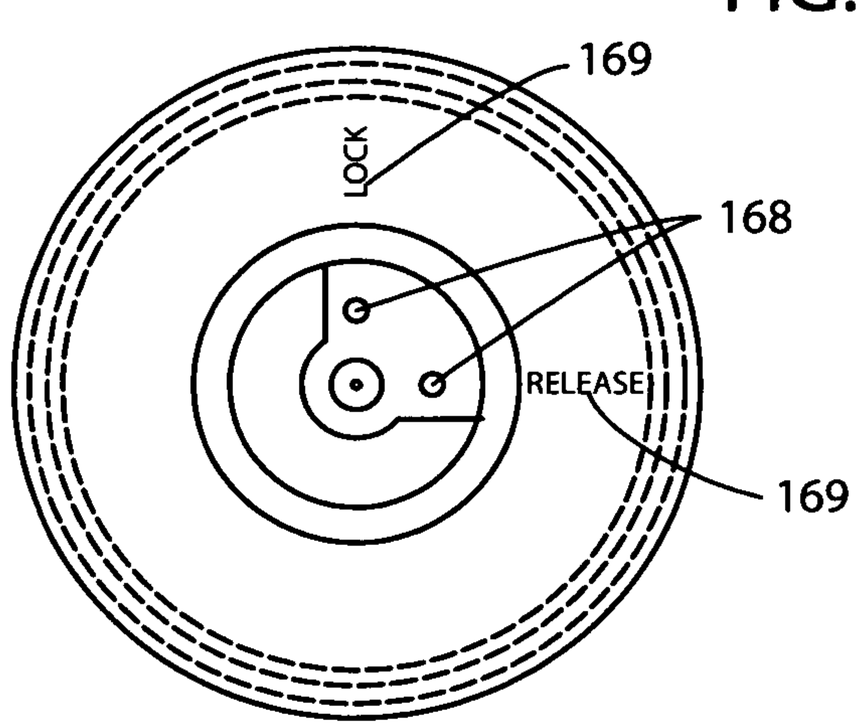


FIG. 52

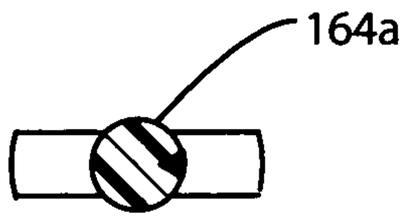


FIG. 54

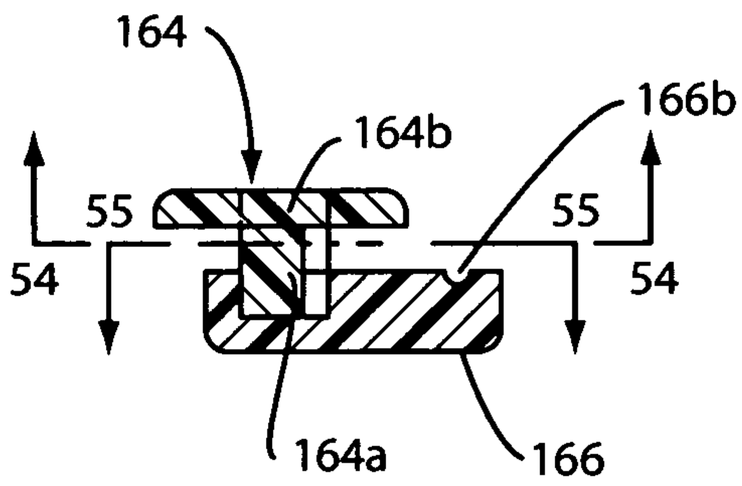


FIG. 53

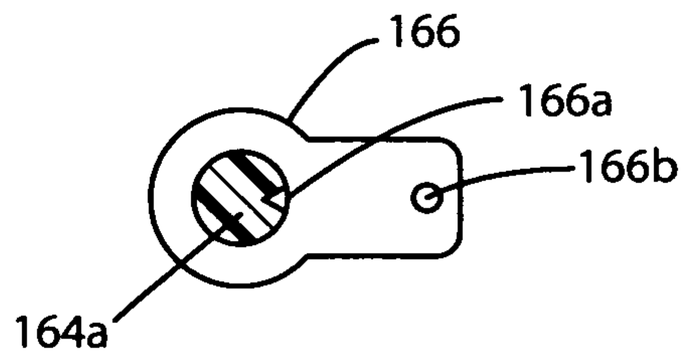
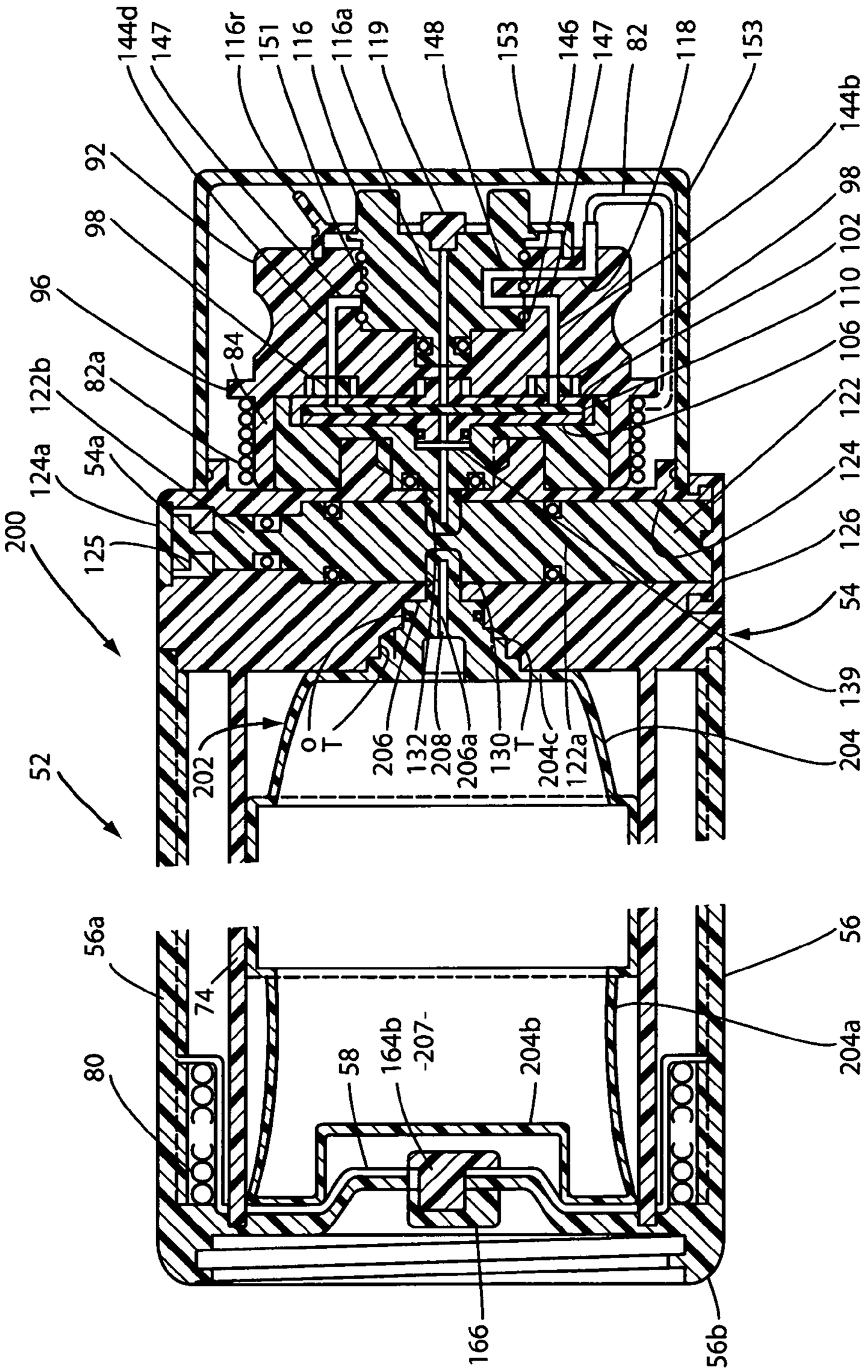


FIG. 55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116r
151
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116a
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153
146
147
82
118
153
144b
92
98
96
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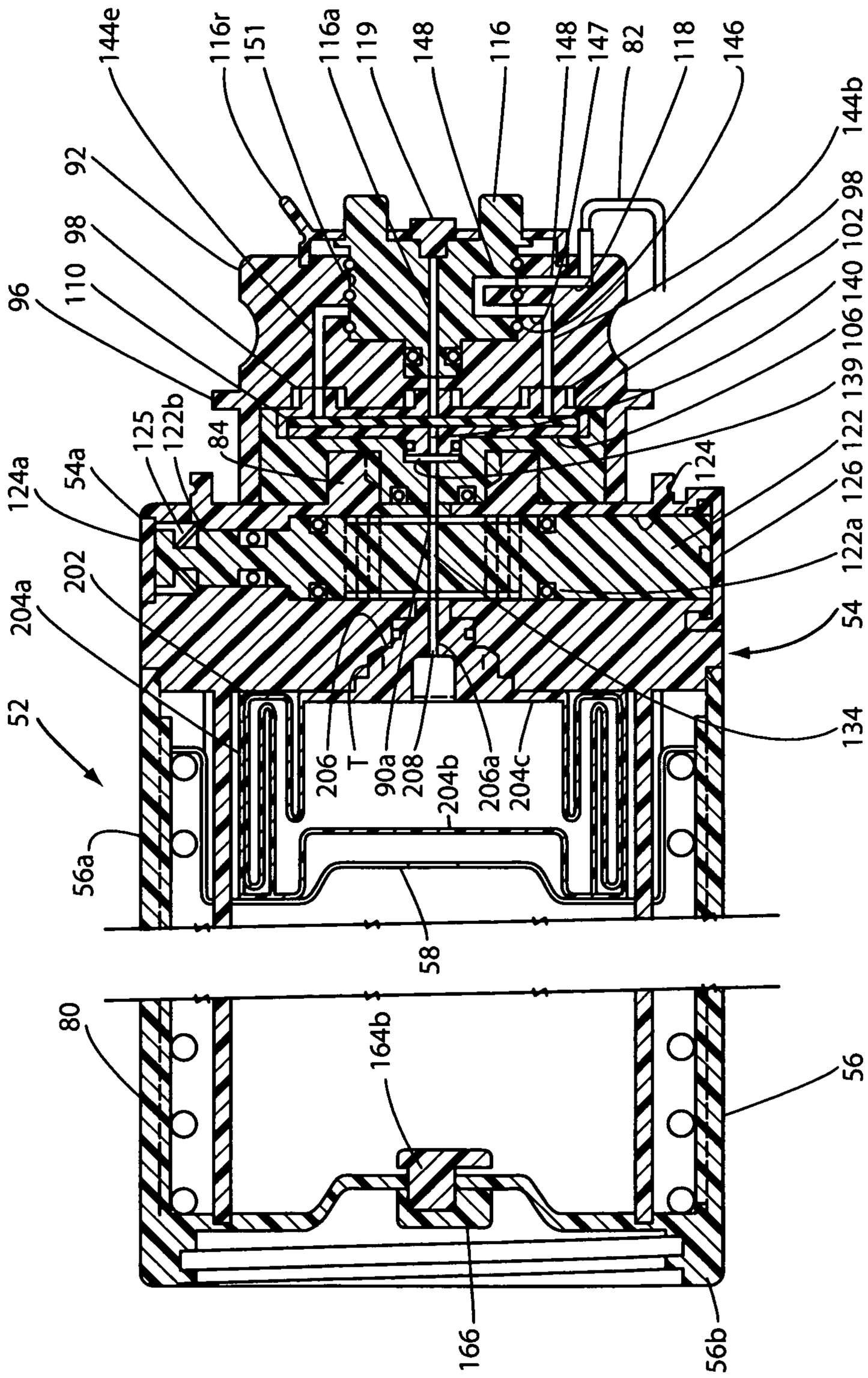
82a
122b
54a
124a
125
200
52
202
O
T
206
132
208
206a
130
T
204c
122a
204
139
54
126
124
122
106
110
102
98
56a
74
80
58
164b
-207-
204b
204a
56
166
56b

FIG. 56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116a
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148
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82
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146
144b
92
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102
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106
139
125
122b
84
122
124a
54a
124
126
202
122a
204a
54
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134
206
T
90a
208
204b
206a
204c
56a
8
80
164b
56
166
56b

FIG. 57

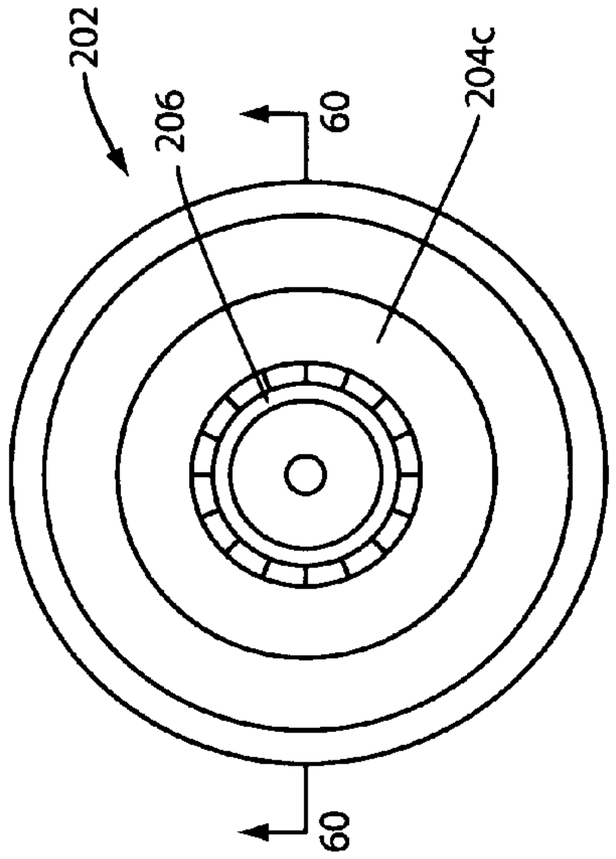


FIG. 59

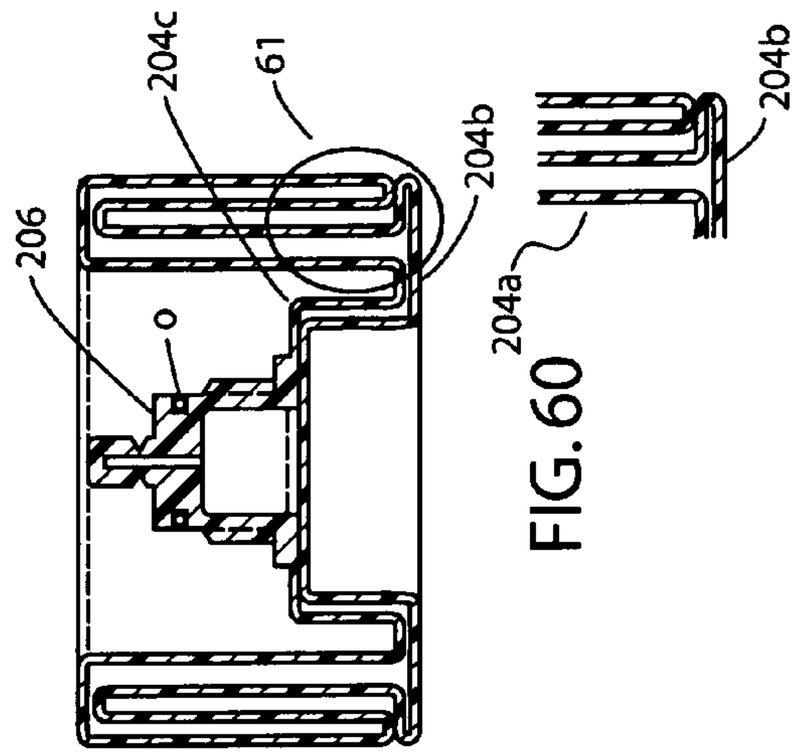


FIG. 60

FIG. 61

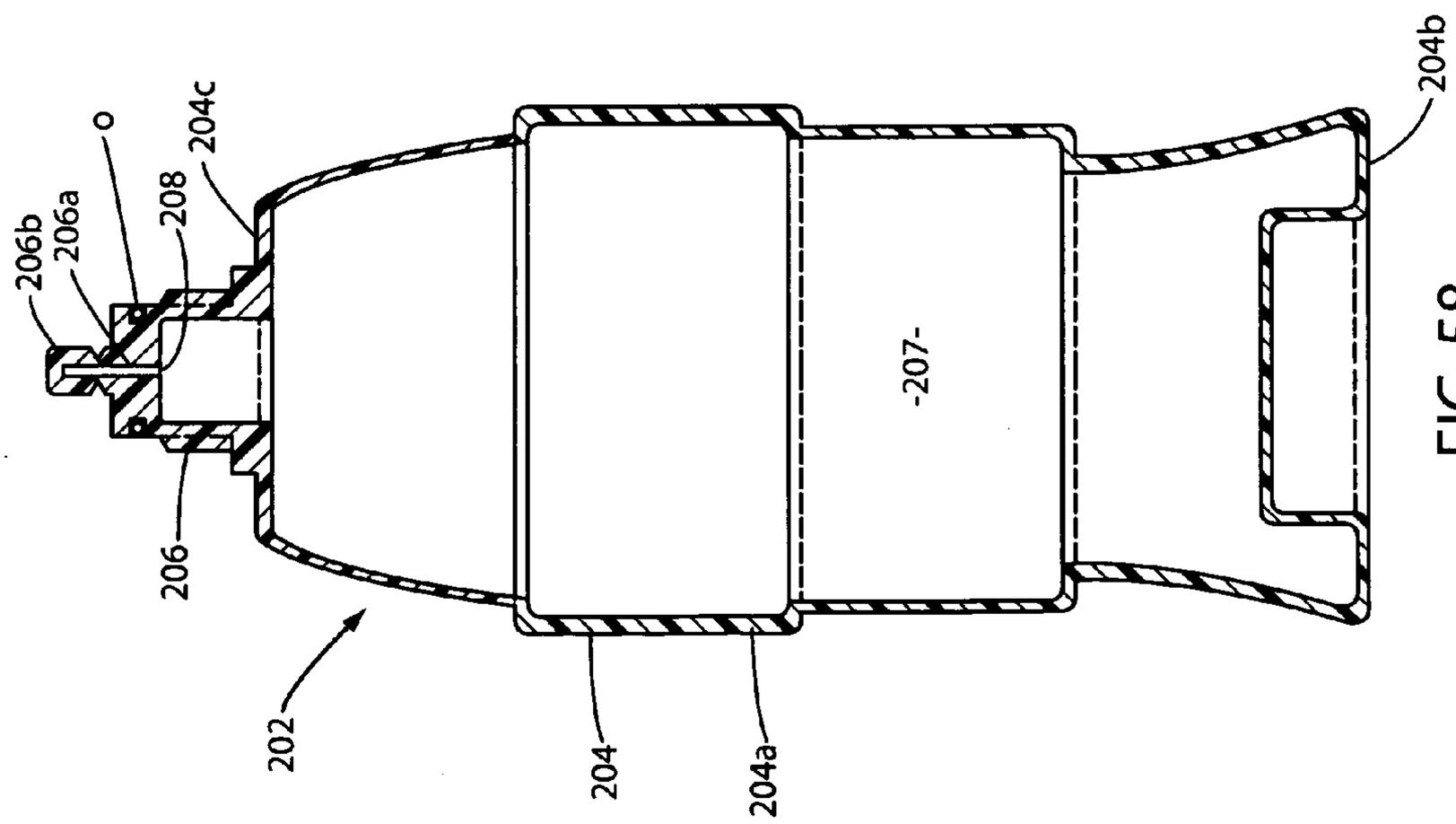


FIG. 58

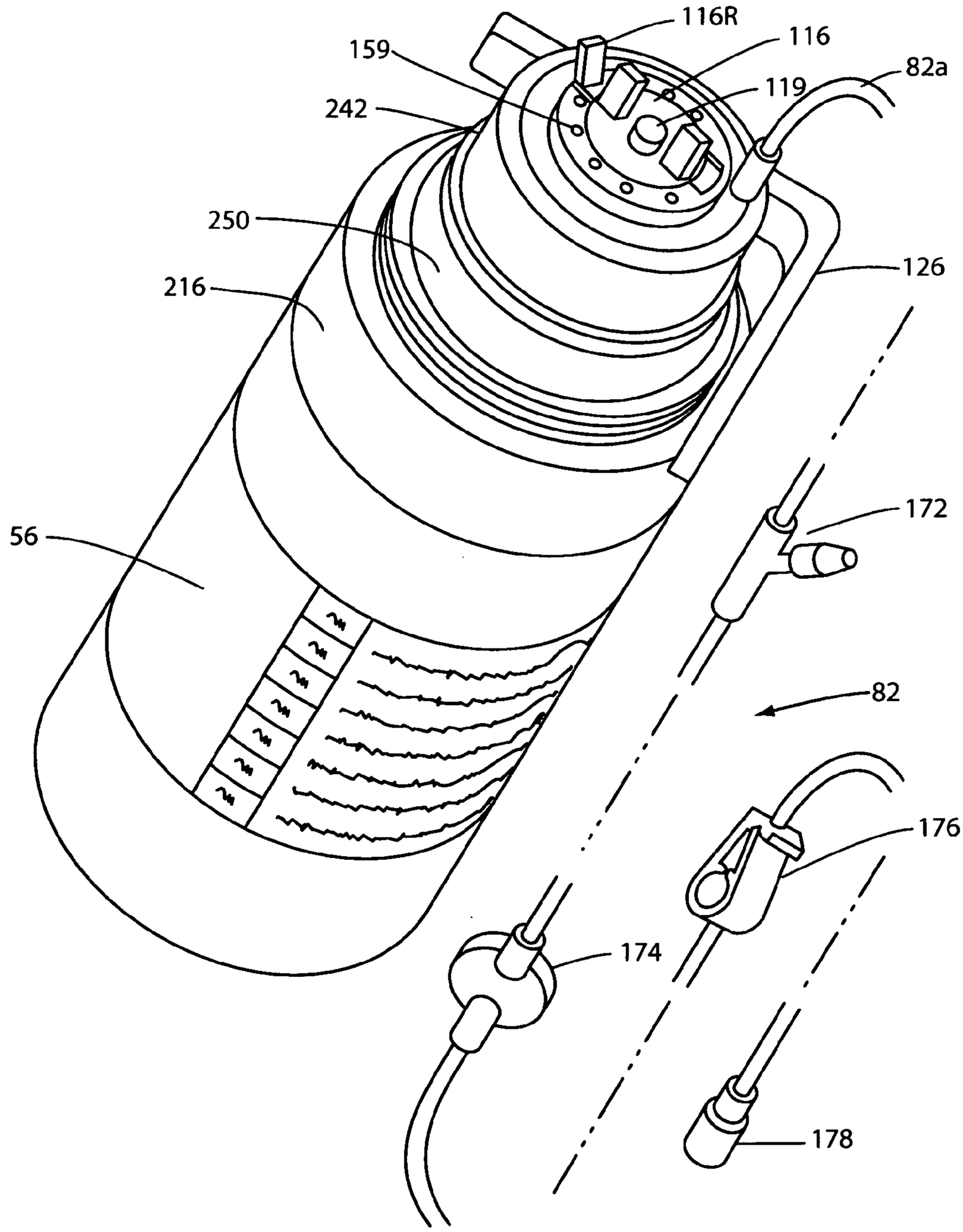
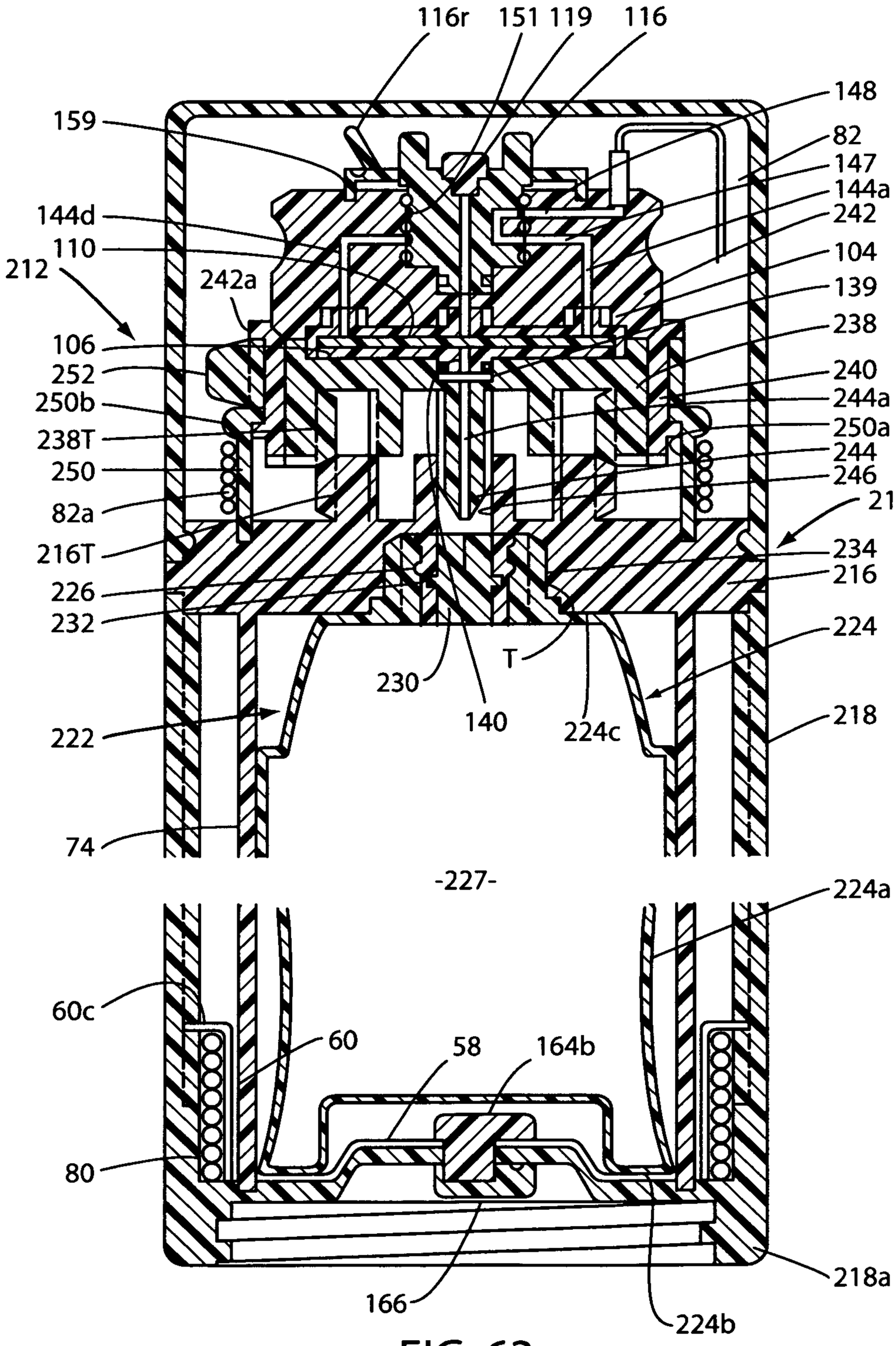


FIG. 62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144a
144d
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110
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212
242a
139
238
106
240
252
244a
250b
250a
238T
244
250
246
82a
214
216T
234
226
216
232
224
T
230
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224c
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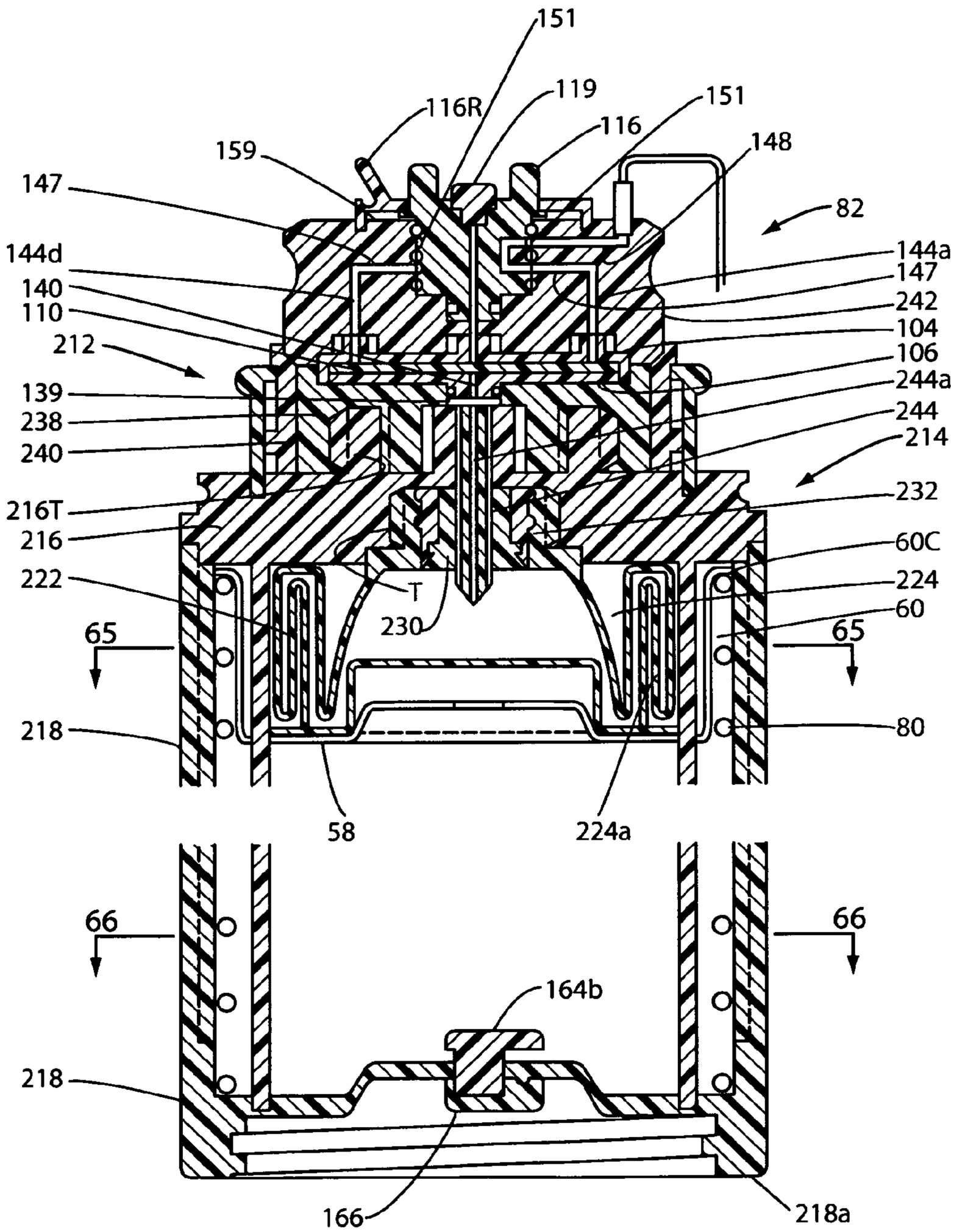
218
74
-227-
224a
60c
60
58
164b
80
218a
166
224b

FIG. 63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116R
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116
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147
82
144d
144a
140
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110
242
104
212
106
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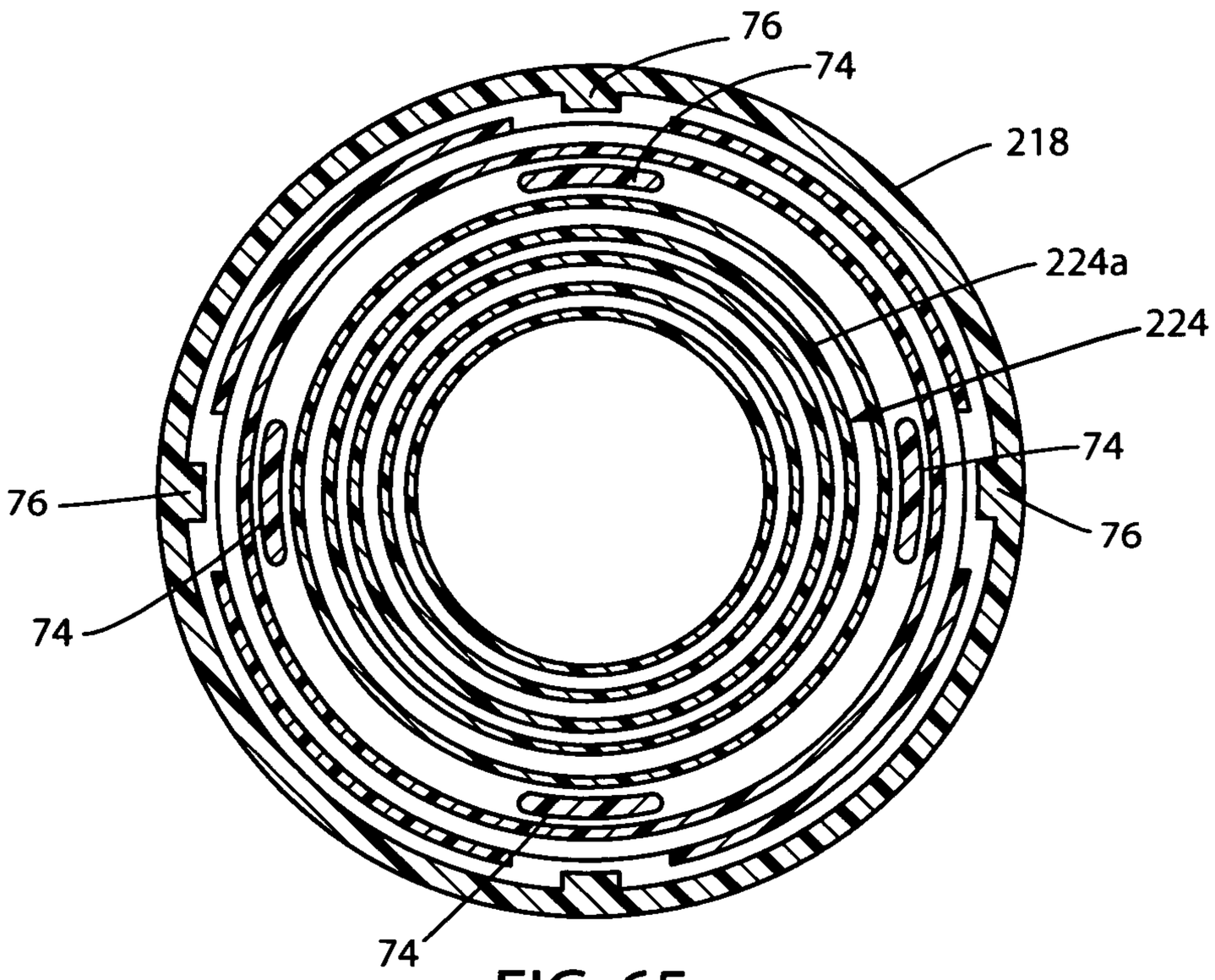
244a
238
244
240
214
216T
232
216
60C
222
224
T
230
60
65
65
218
80
58
224a
66
66
164b
218
166
218a

FIG. 64


76
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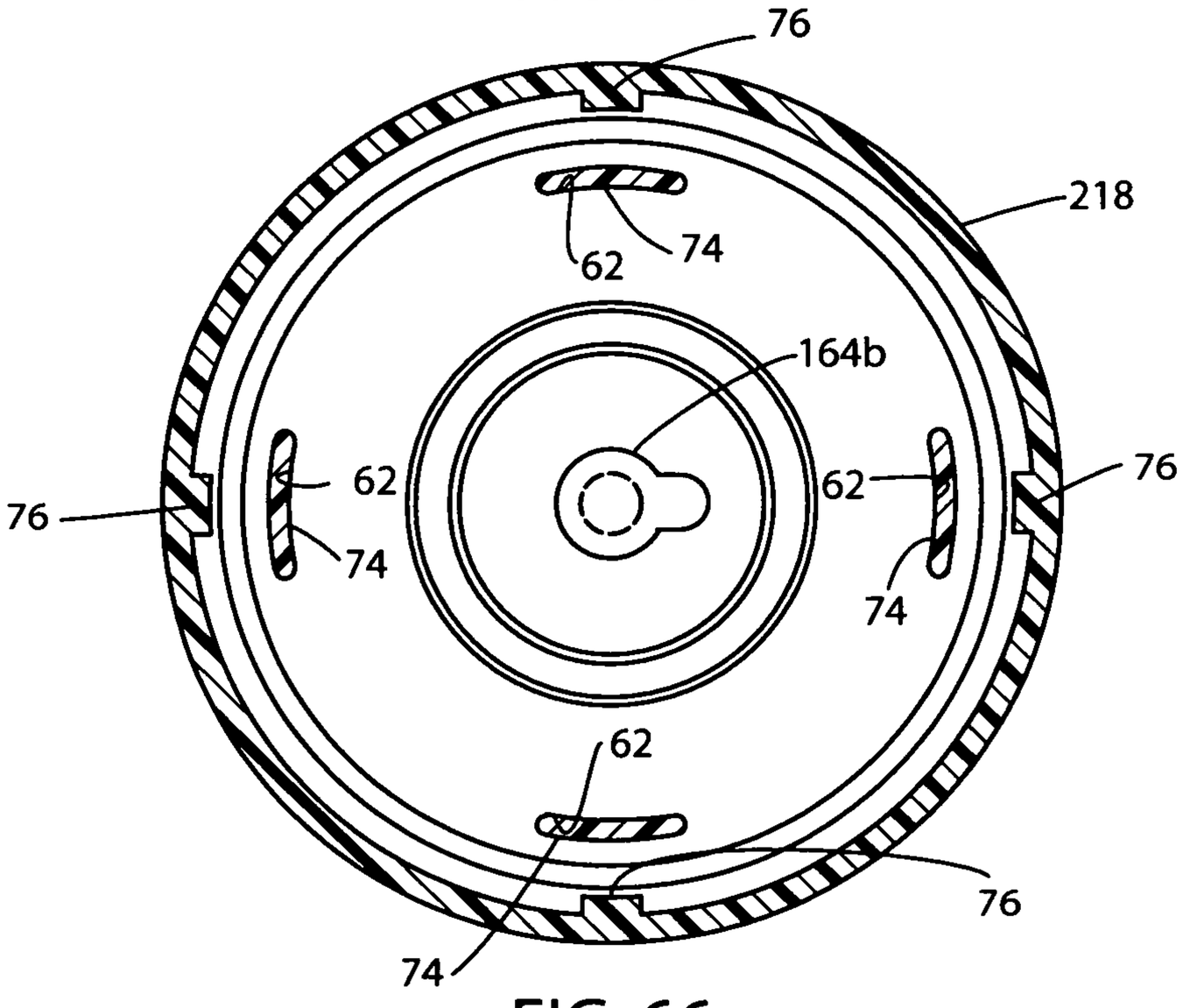
218
224a
224
74
76
76
74
74

FIG. 65


76
218
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164b
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62
76
76
74
74
62
76
74

FIG. 66

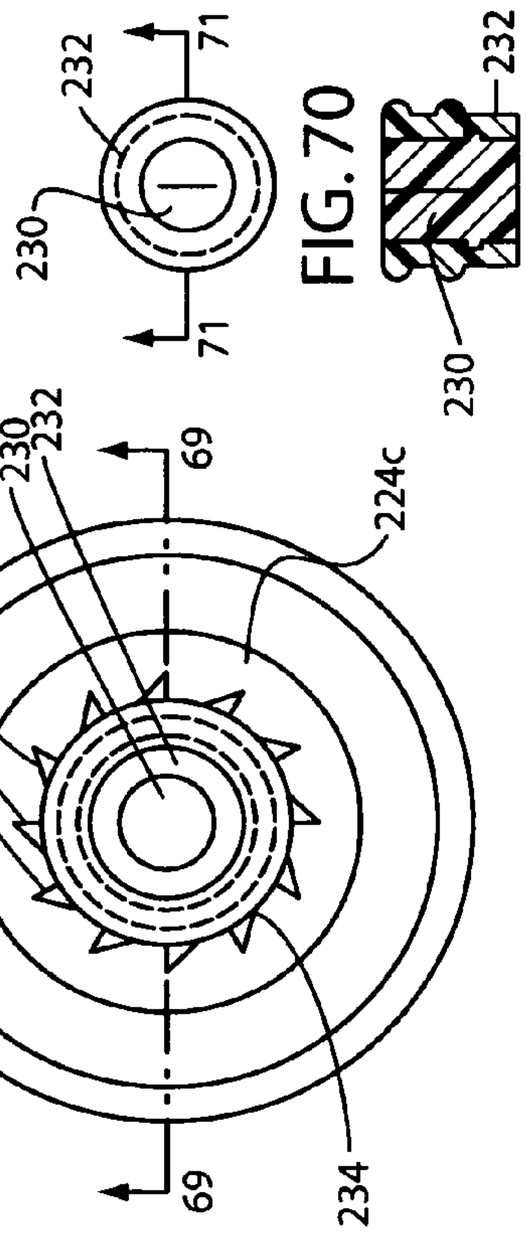


FIG. 70

FIG. 71

FIG. 68

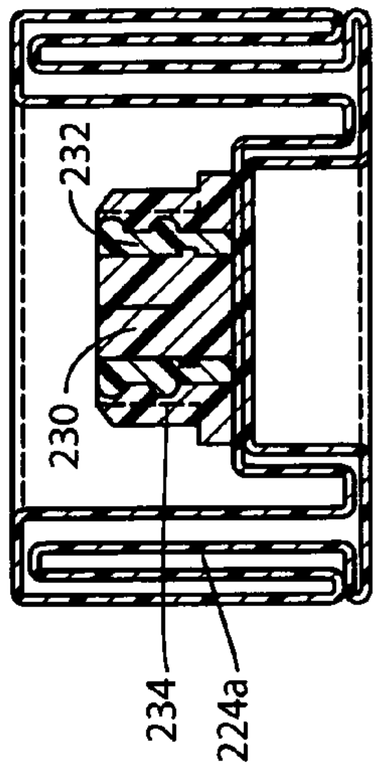


FIG. 69

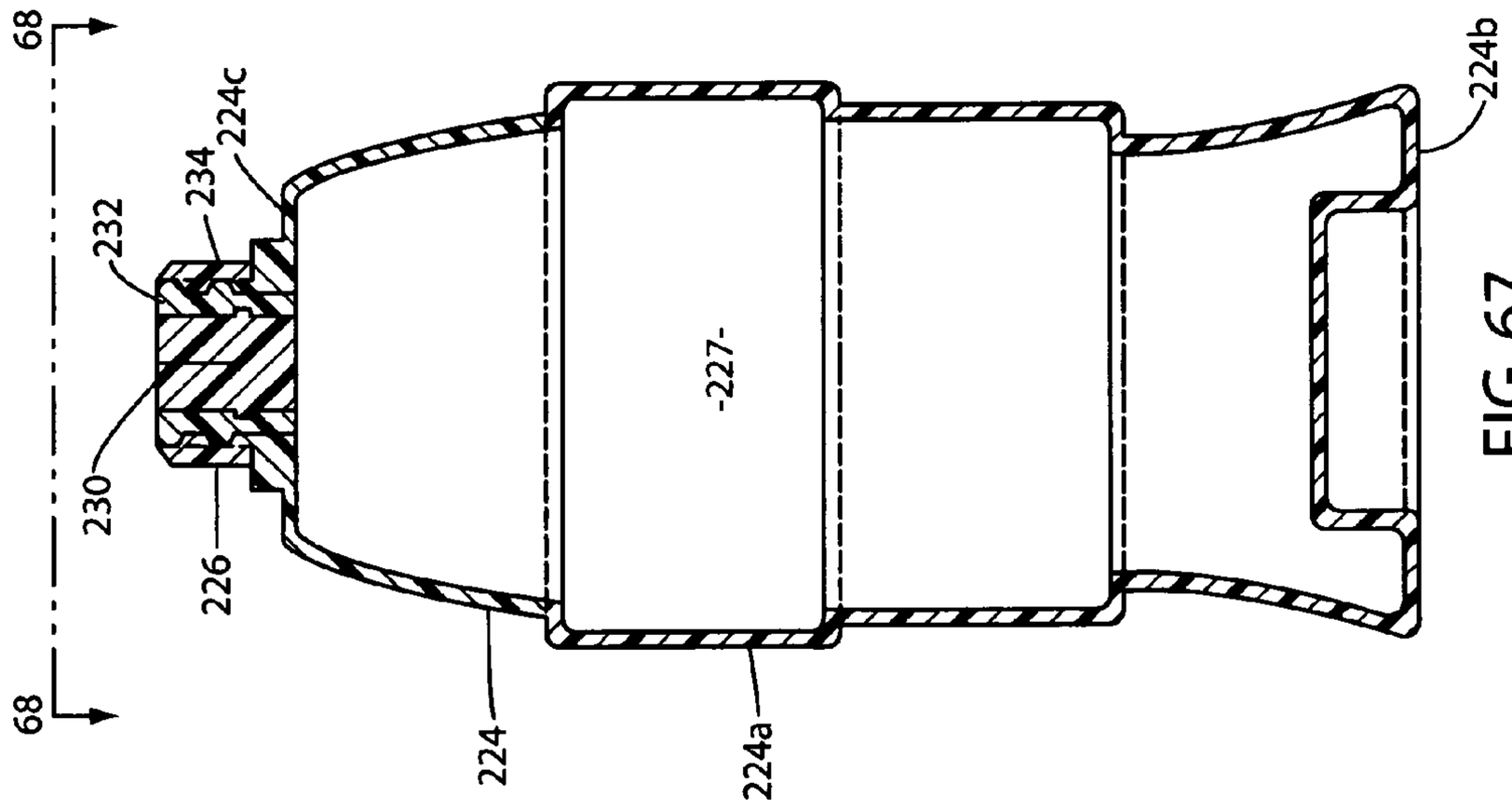


FIG. 67

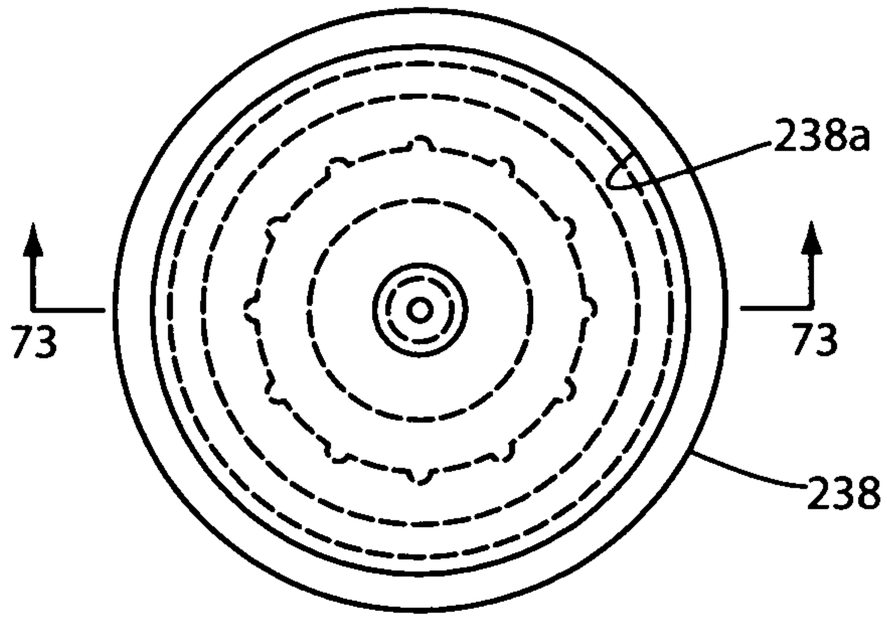


FIG. 72

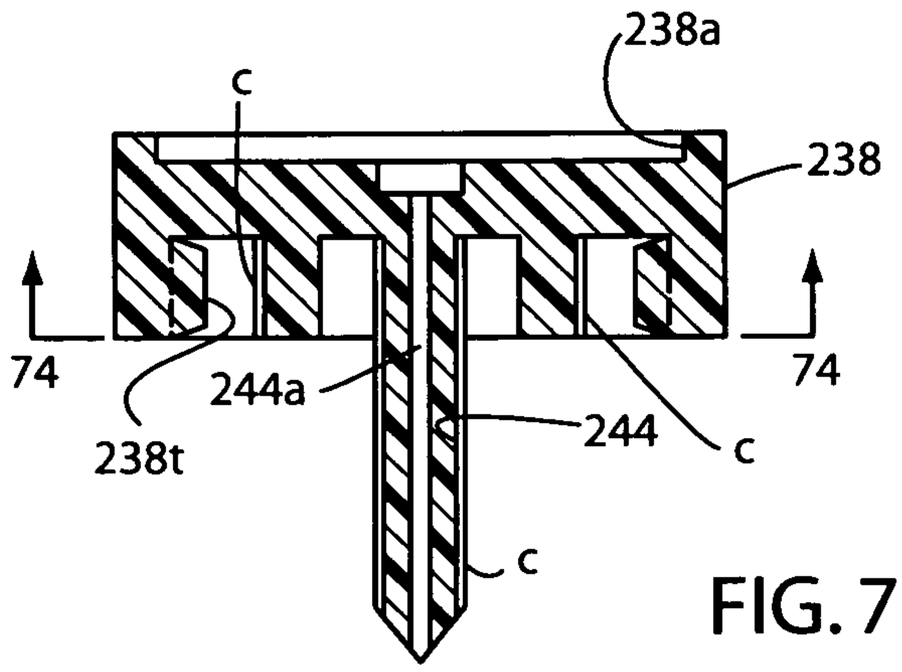


FIG. 73

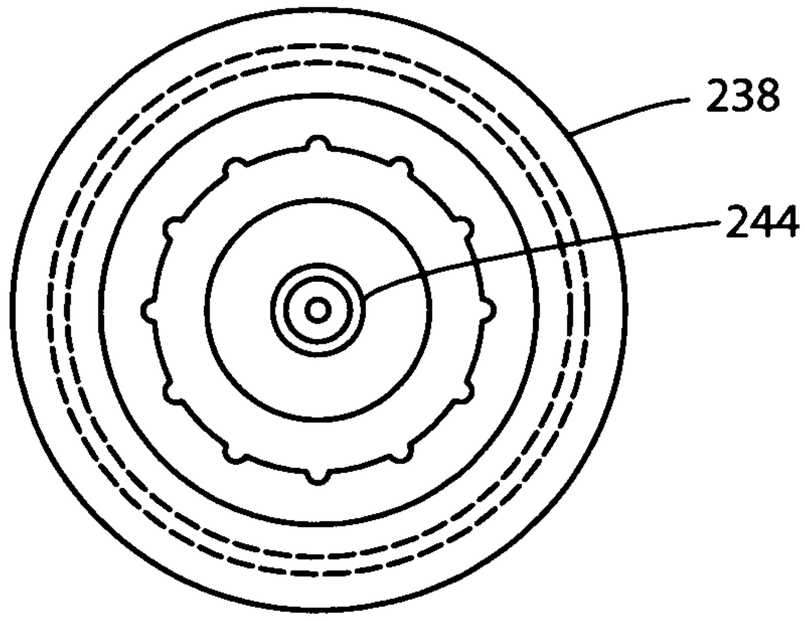


FIG. 74

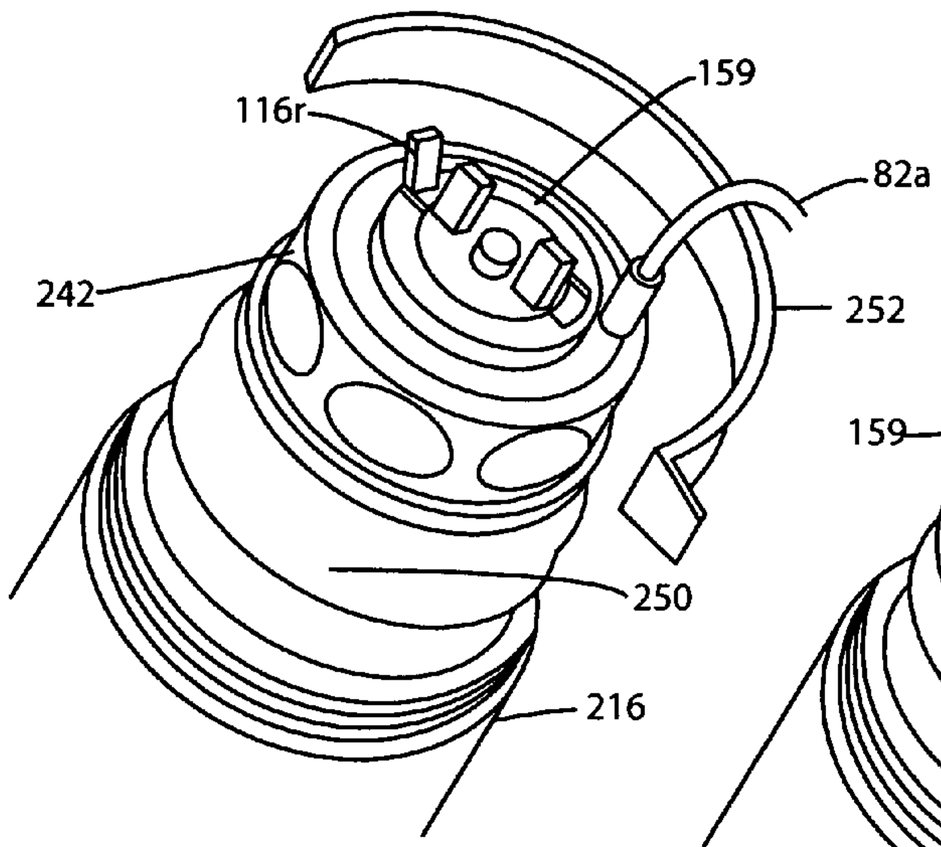
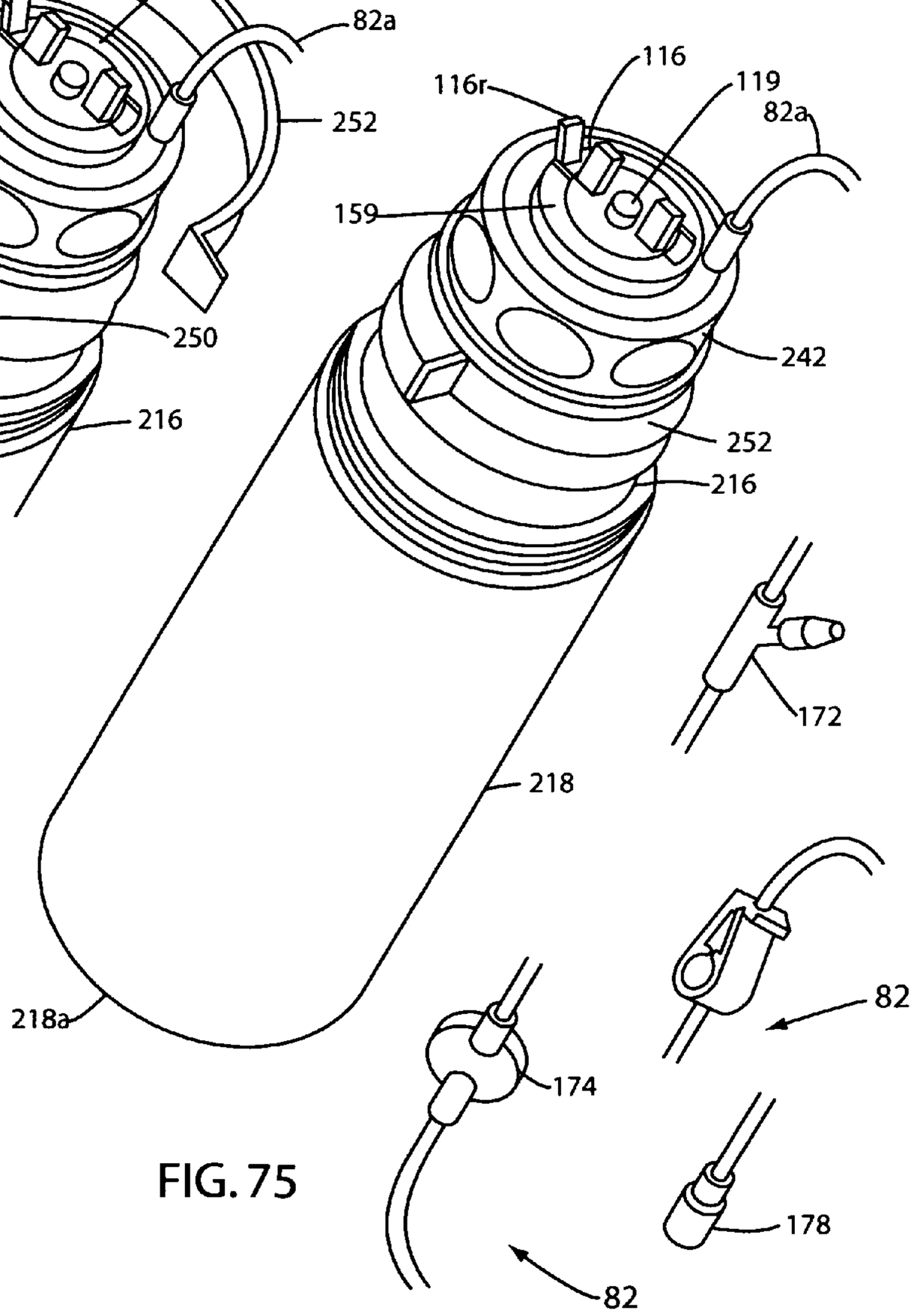

116r
159
82a
242
252
250
216

FIG. 76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218a
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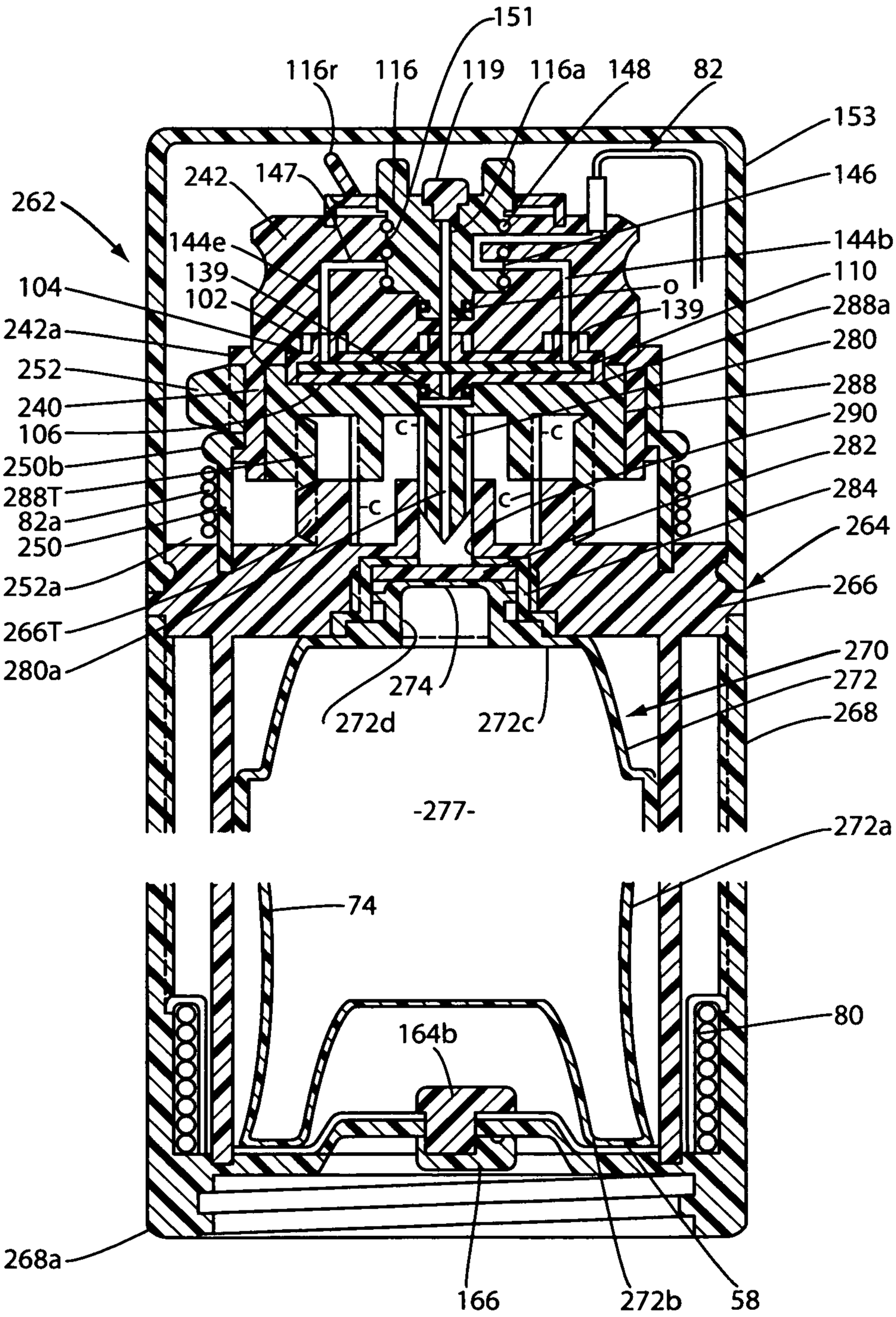
174
178
82

FIG. 75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139
288a
242a
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250b
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288T
82a
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252a
266
266T
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272d
272c
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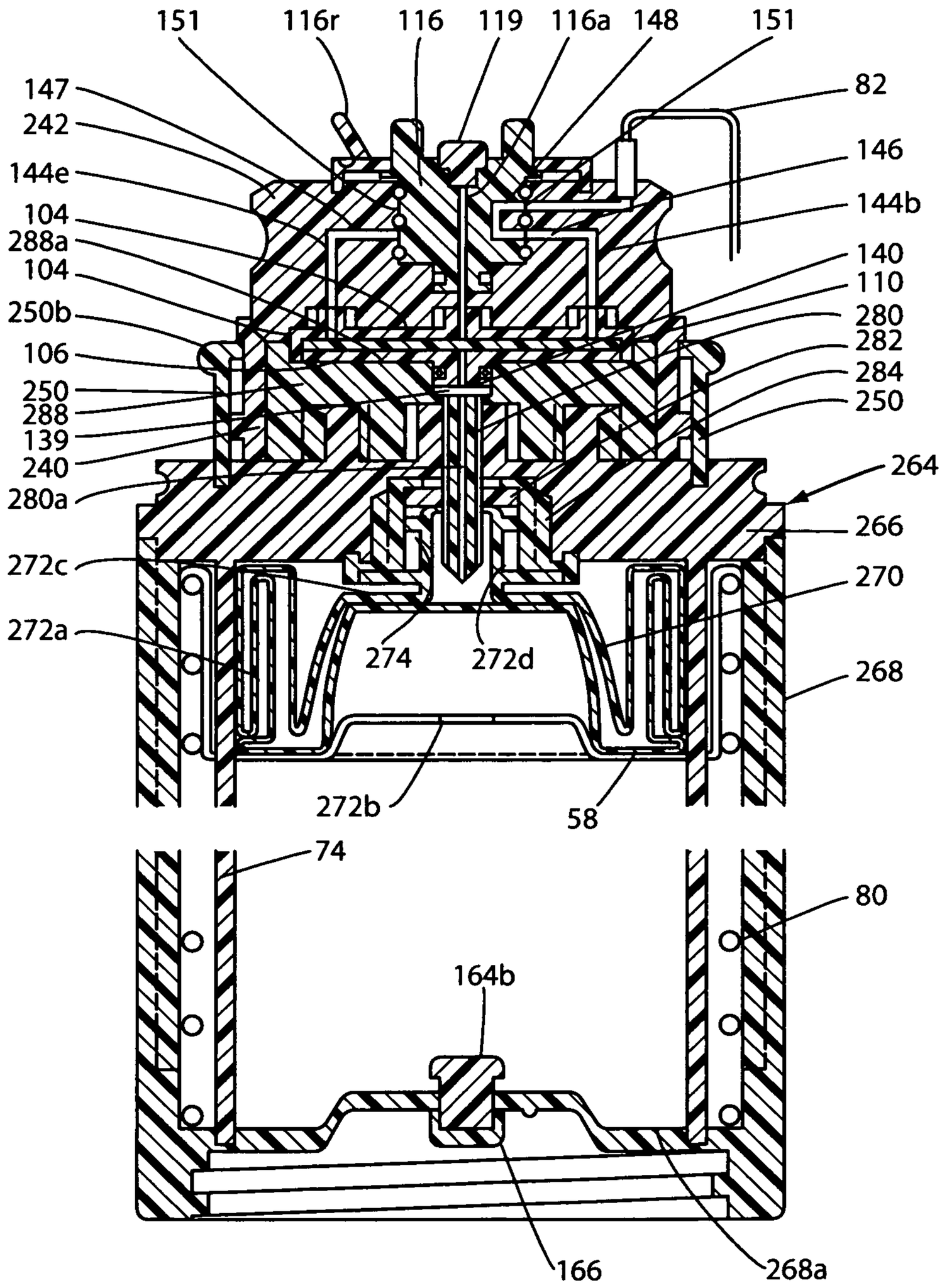
-277-
272a
74
80
164b
268a
166
272b
58

FIG. 77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288a
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250b
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280a
272c
272a
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144b
140
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272d
272b
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164b
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268a

FIG. 78

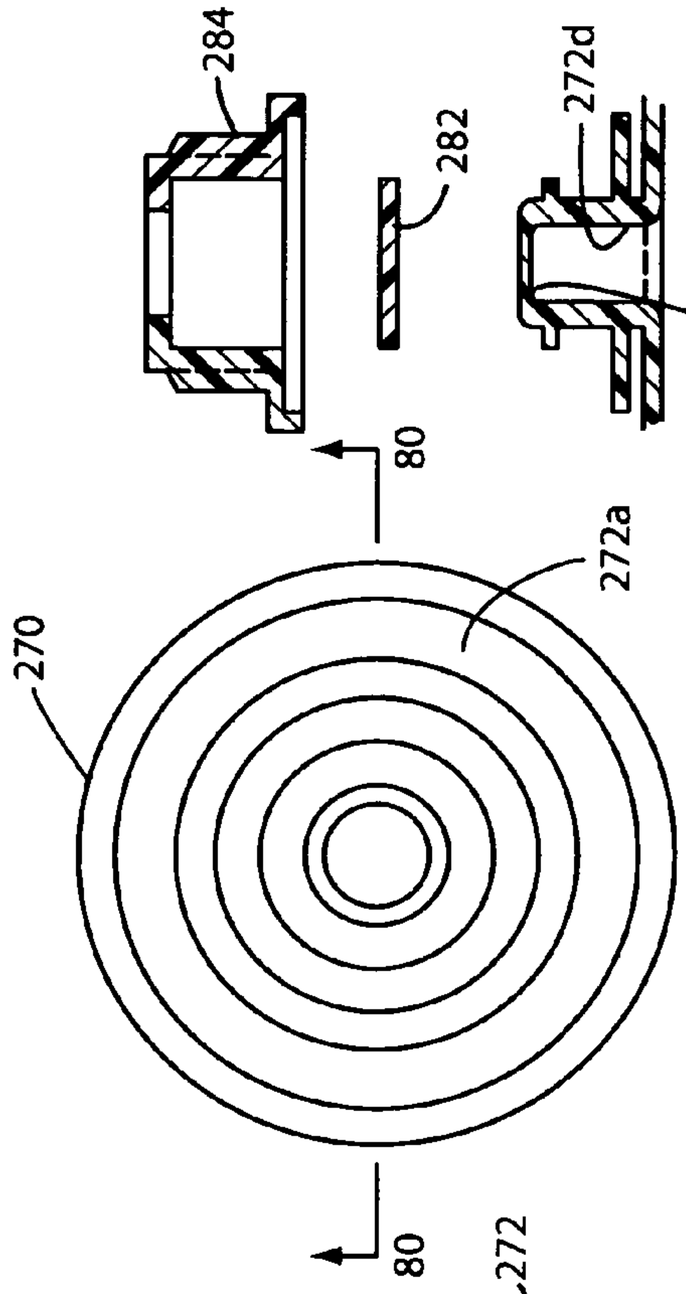


FIG. 81

FIG. 79

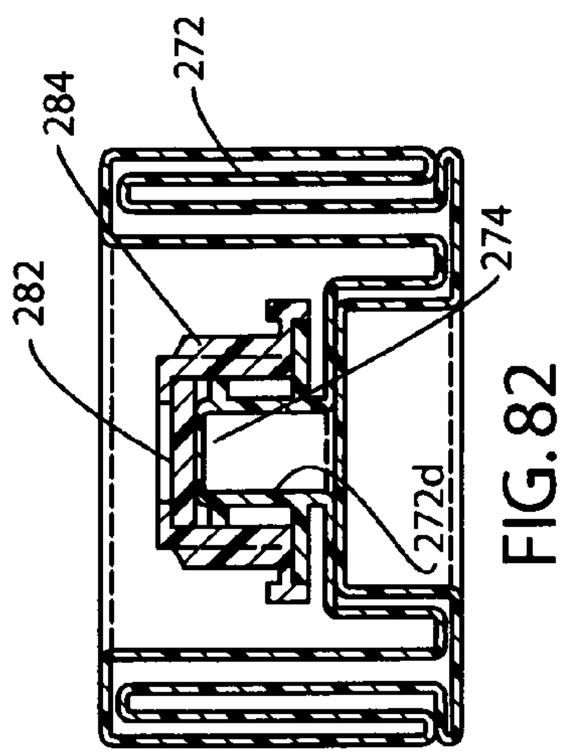


FIG. 82

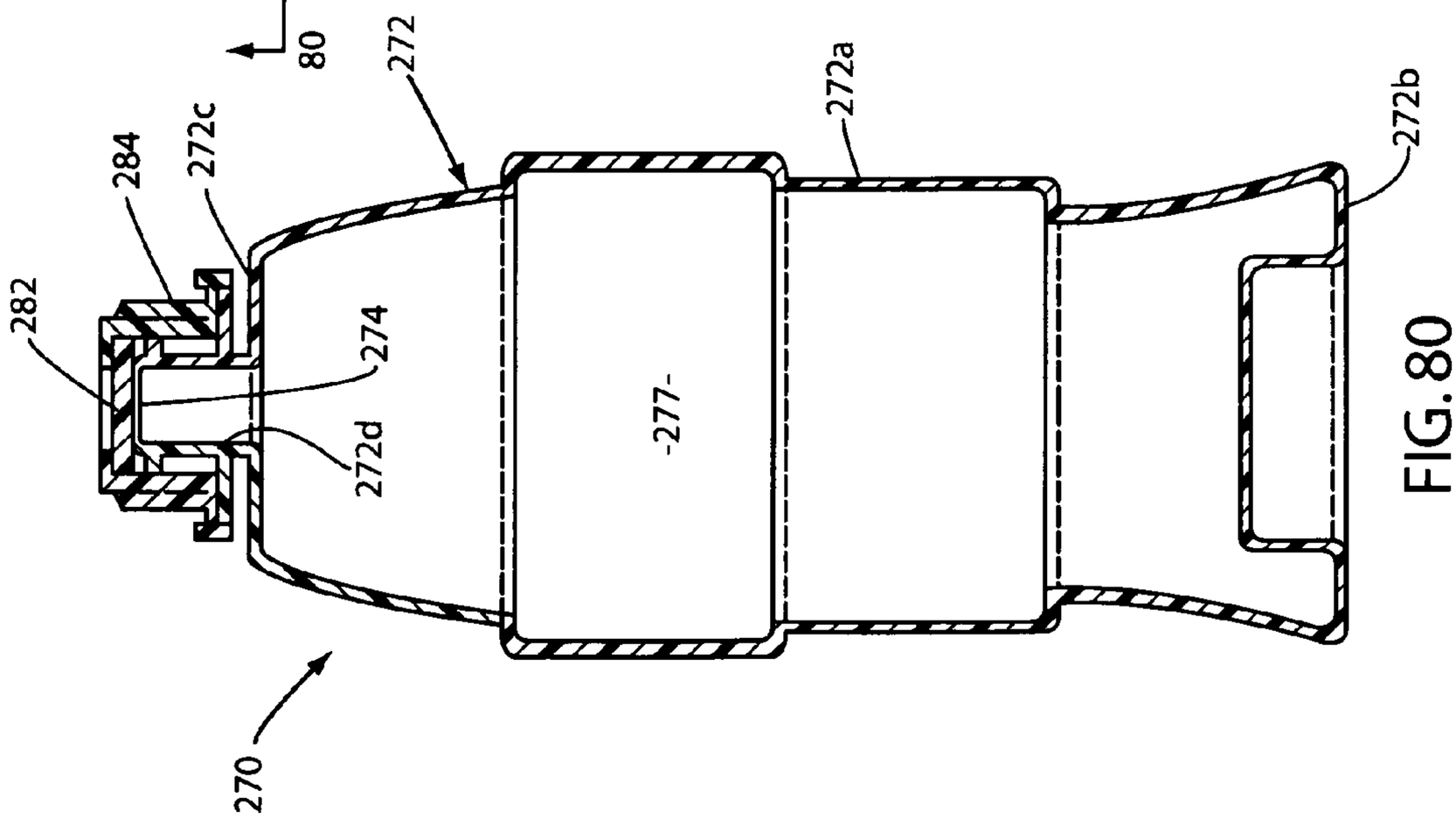
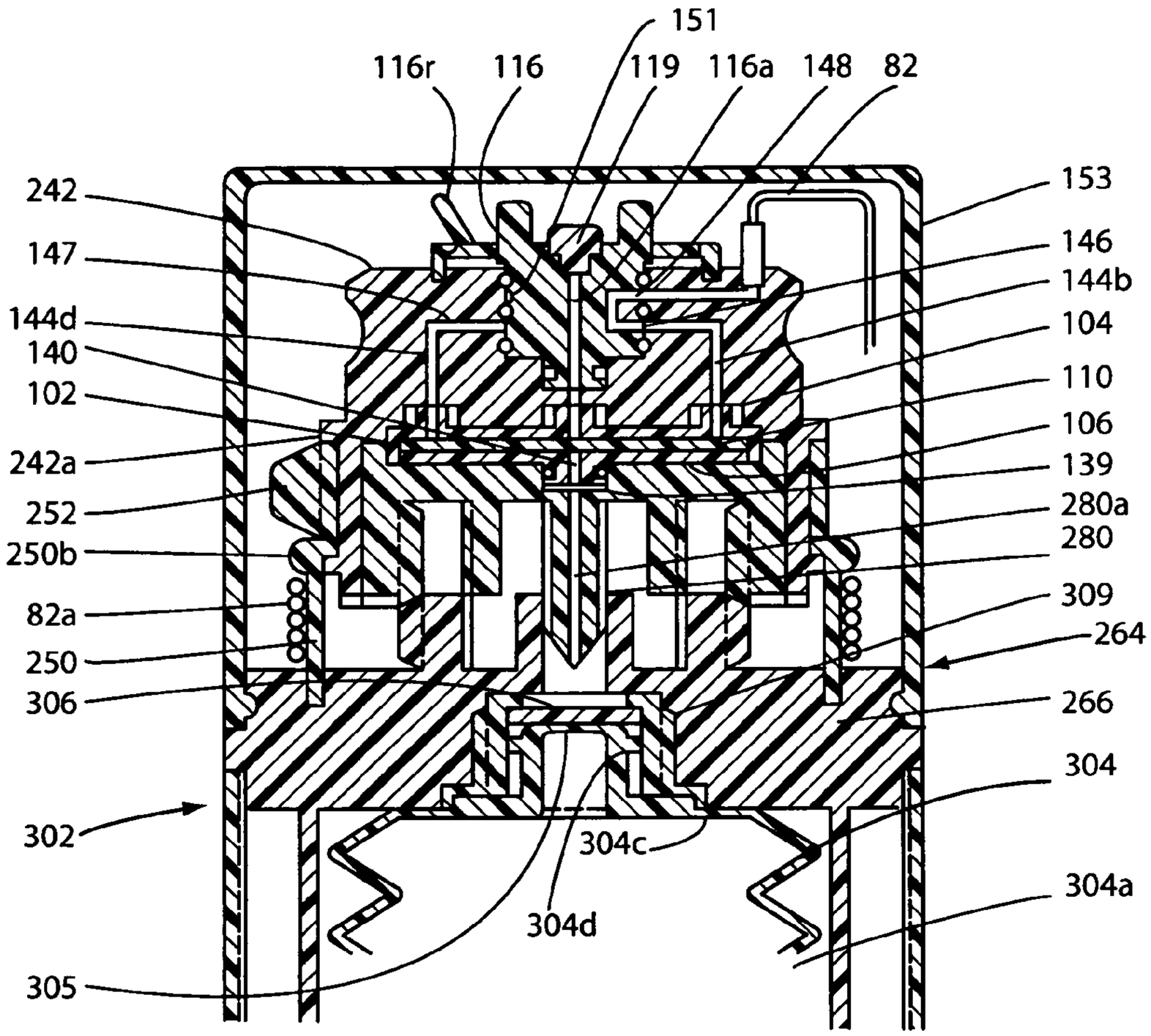


FIG. 80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116r
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116a
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144b
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140
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106
139
242a
280a
252
280
250b
309
82a
264
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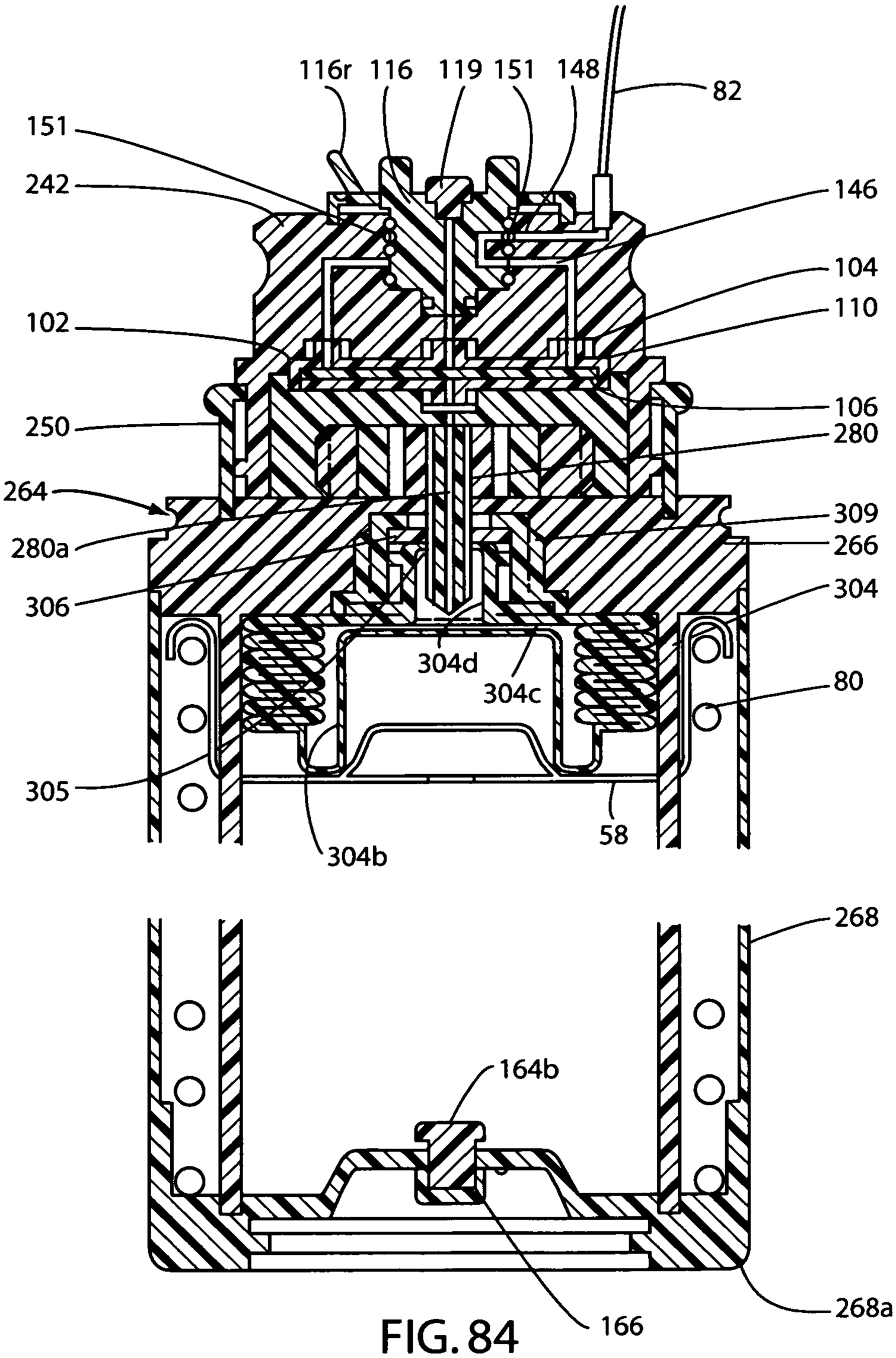
304c
304a
304d
305
-307-
268
80
164b
268a
166
304b
58

FIG. 83


116r
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304d
304c
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304b
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164b
166
268a

FIG. 84

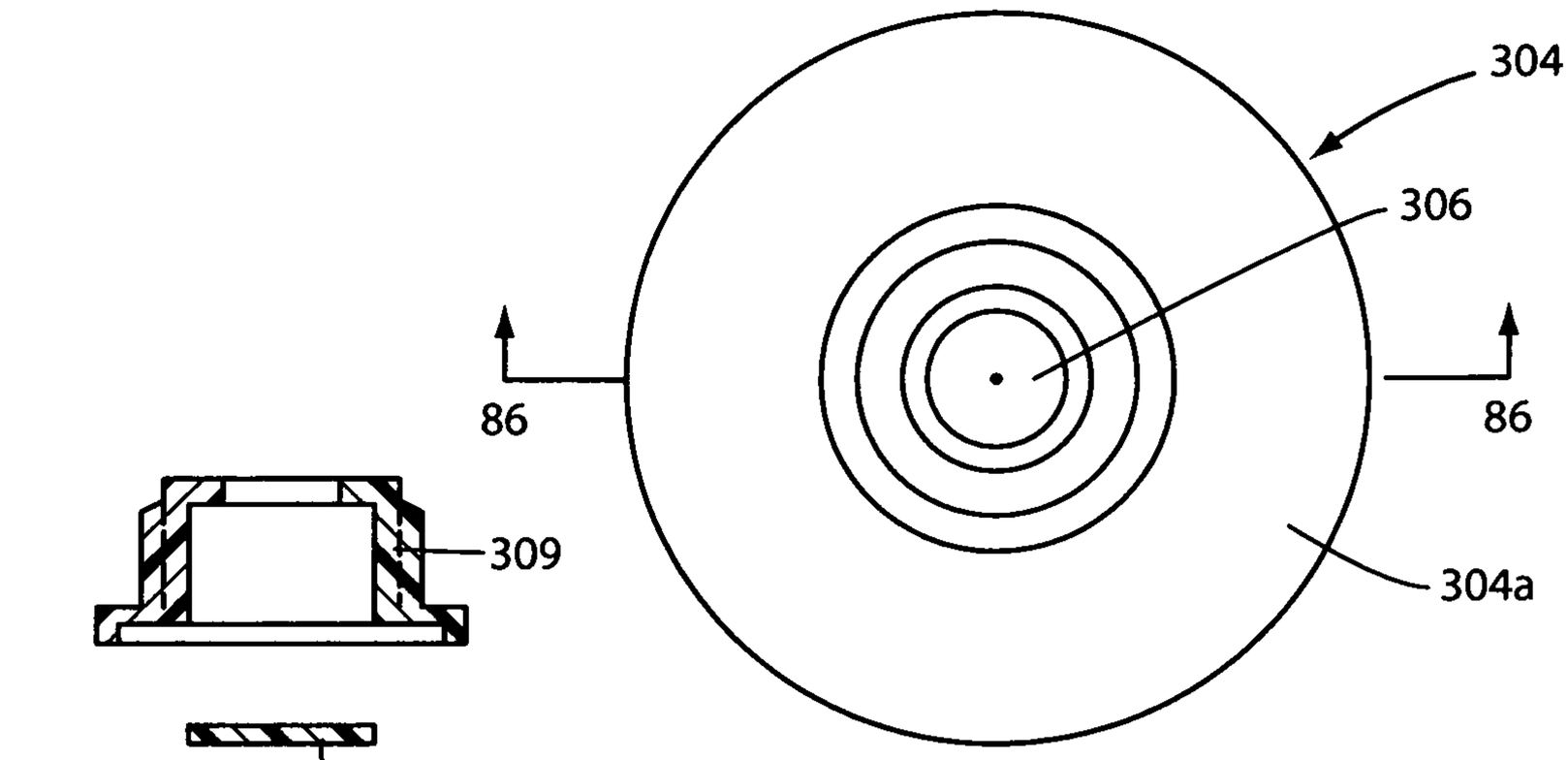


FIG. 85

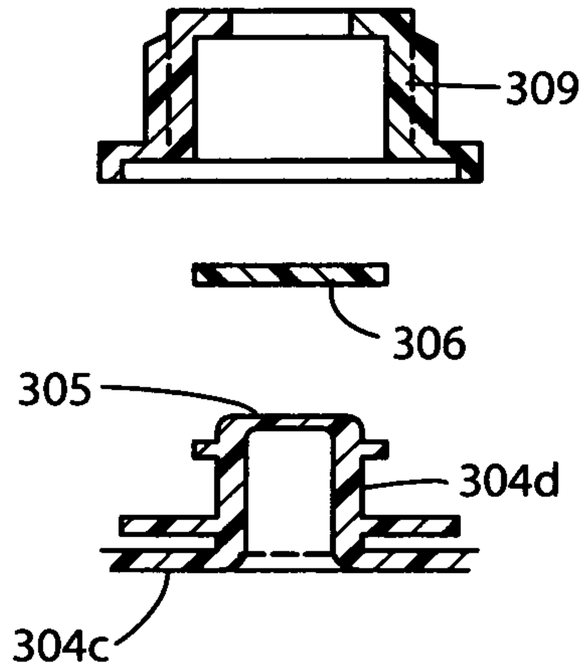
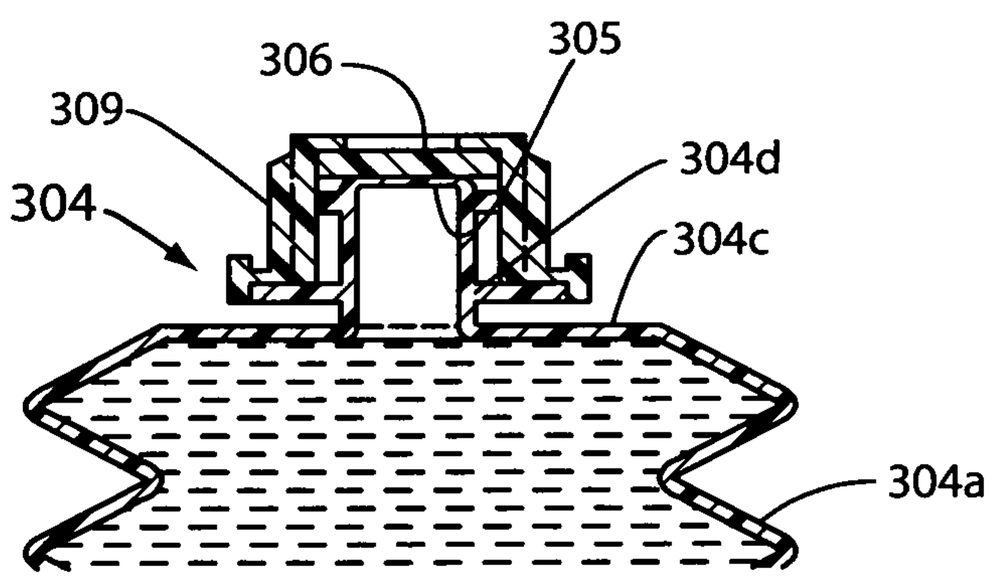


FIG. 87



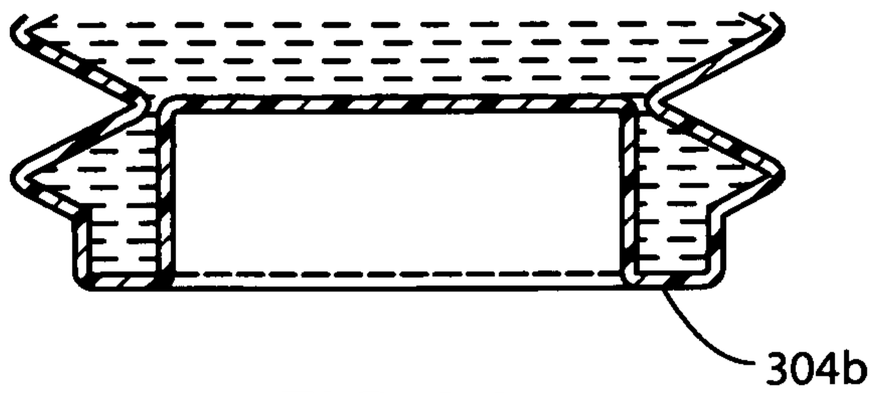
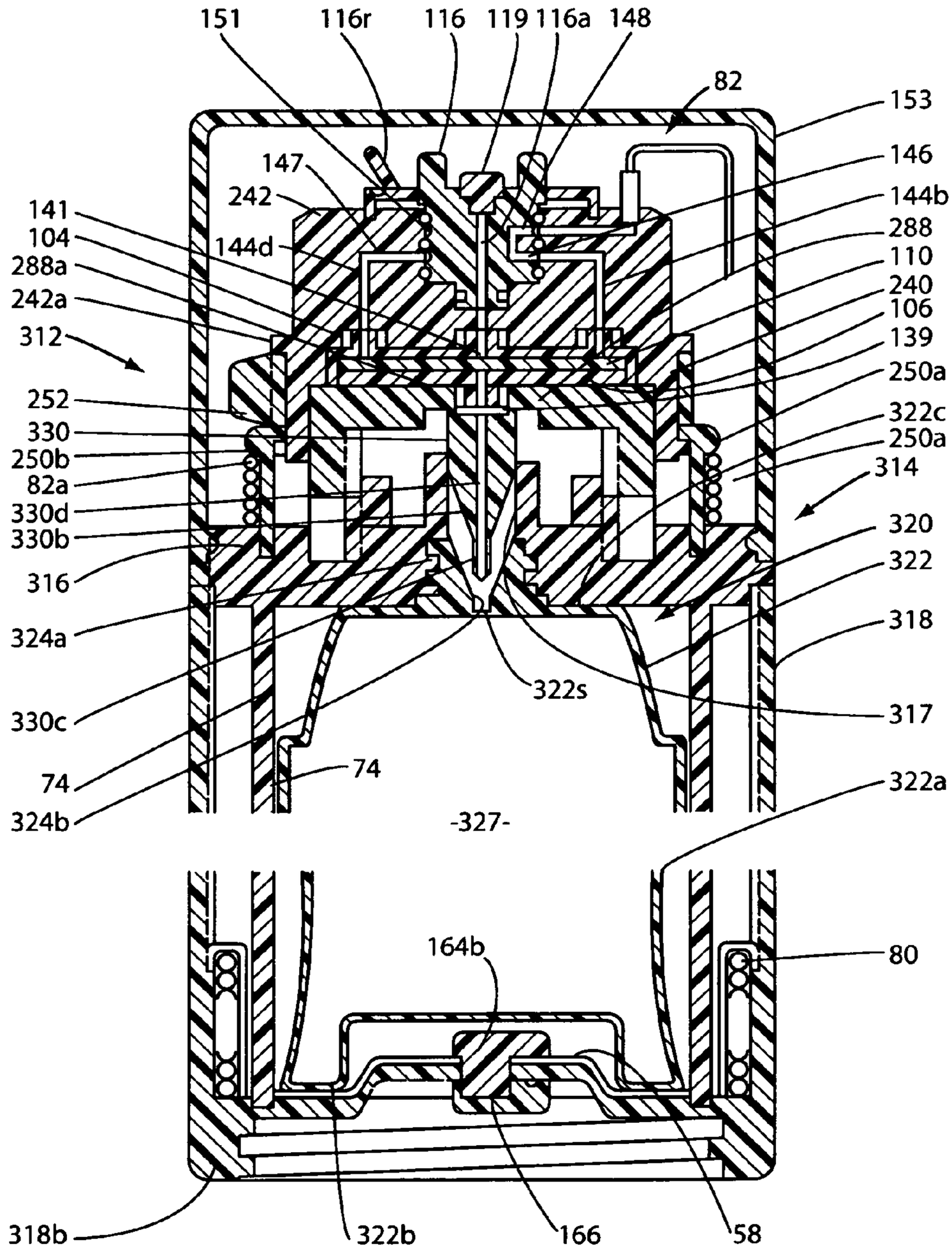


FIG. 86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242a
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312
139
250a
252
322c
330
250a
250b
314
82a
330d
320
330b
322
316
318
324a
322s
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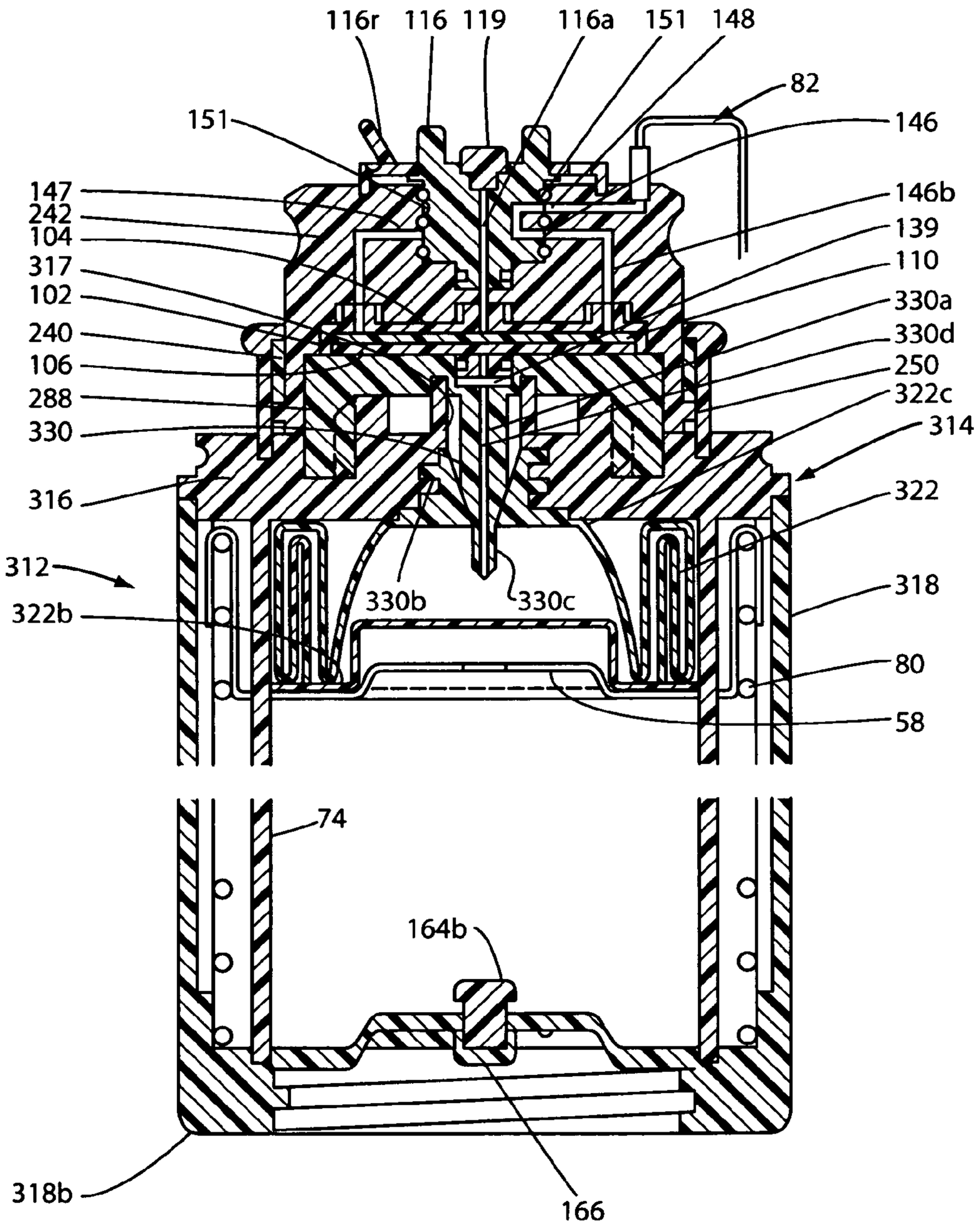
330c
74
74
322a
324b
-327-
164b
80
318b
322b
166
58

FIG. 88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146b
139
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330a
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322c
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322
318
330b
330c
80
58
74
164b
318b
166

FIG. 89

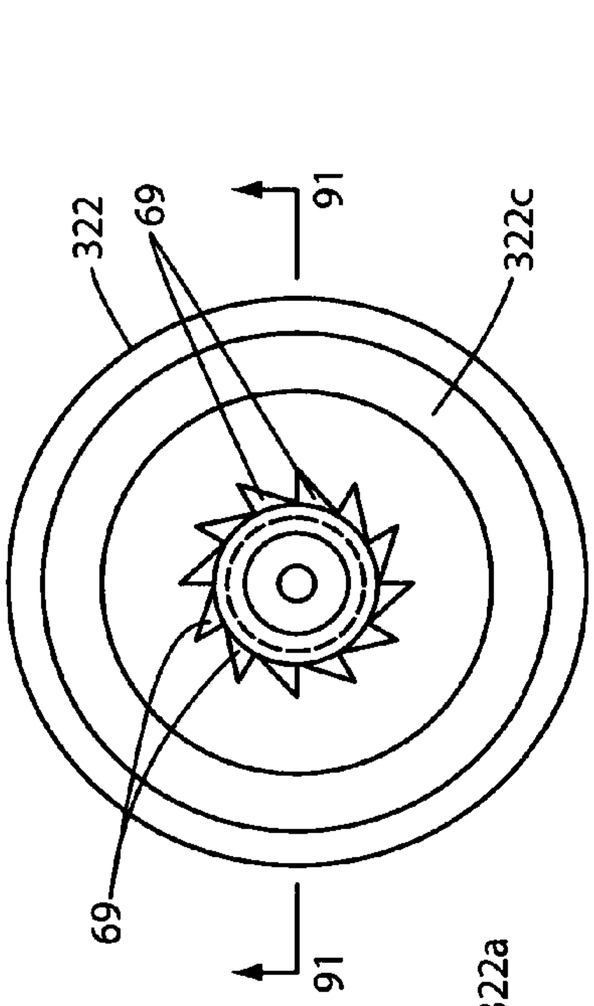


FIG. 90

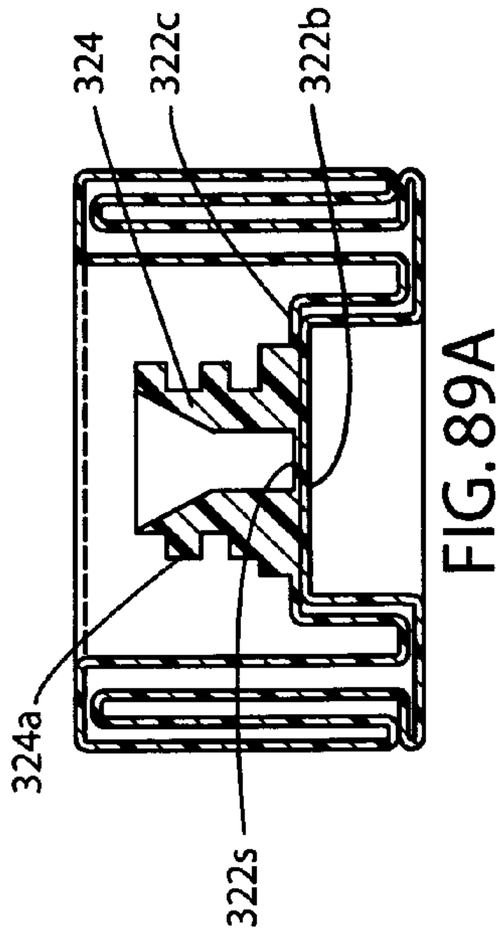


FIG. 89A

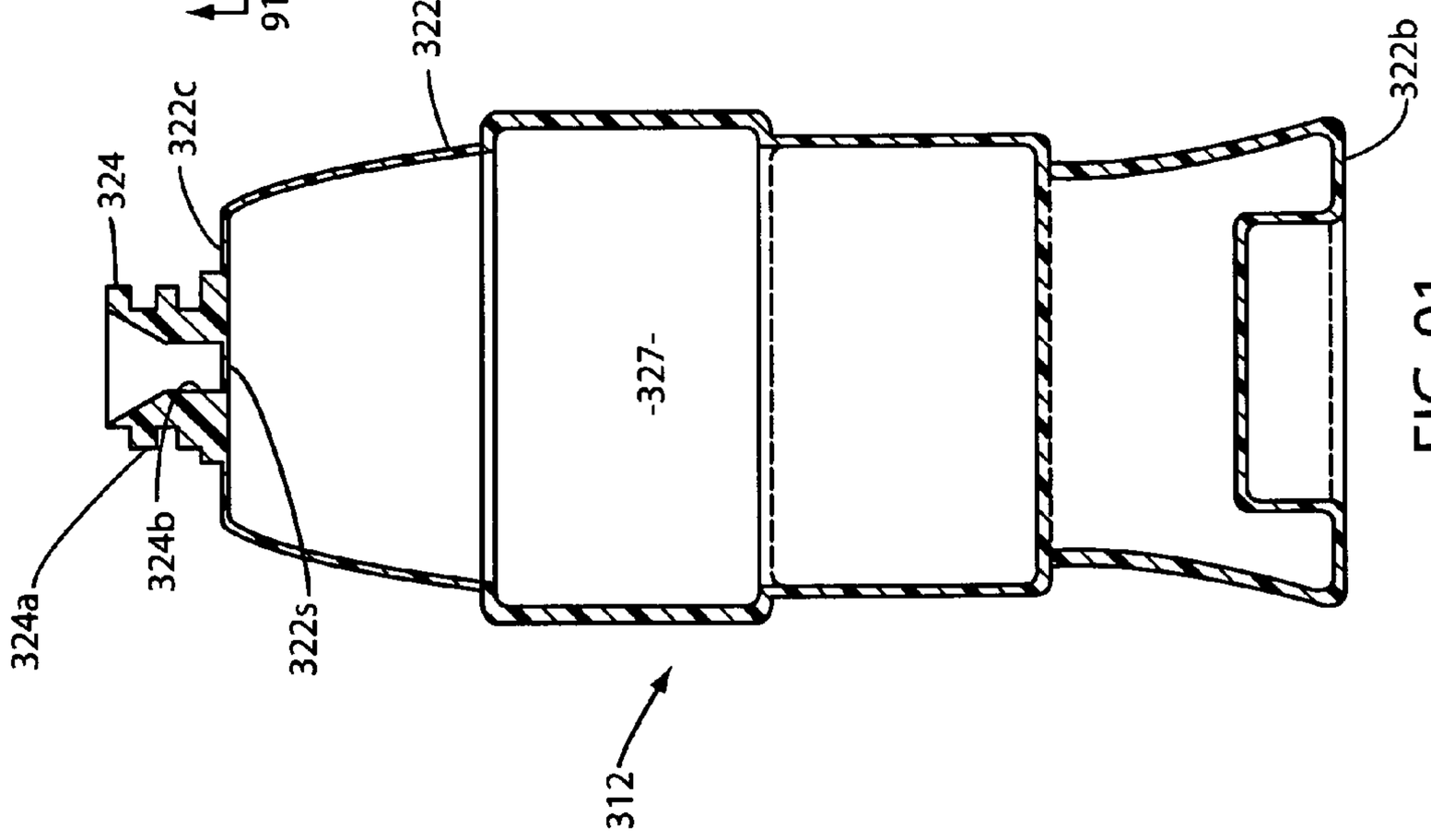
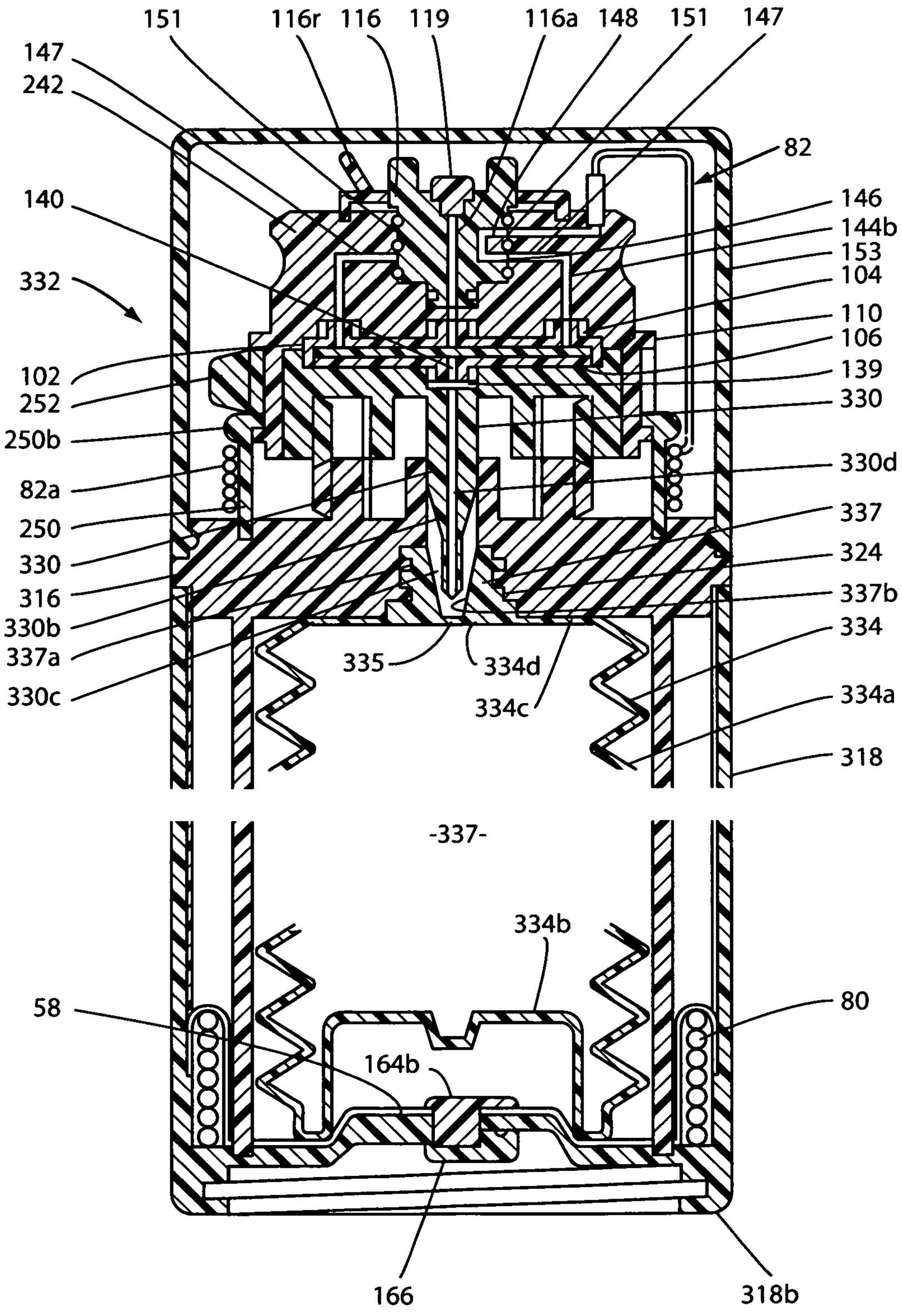


FIG. 91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252
330
250b
330d
82a
337
250
324
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337b
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330b
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334d
337a
334c
334a
330c
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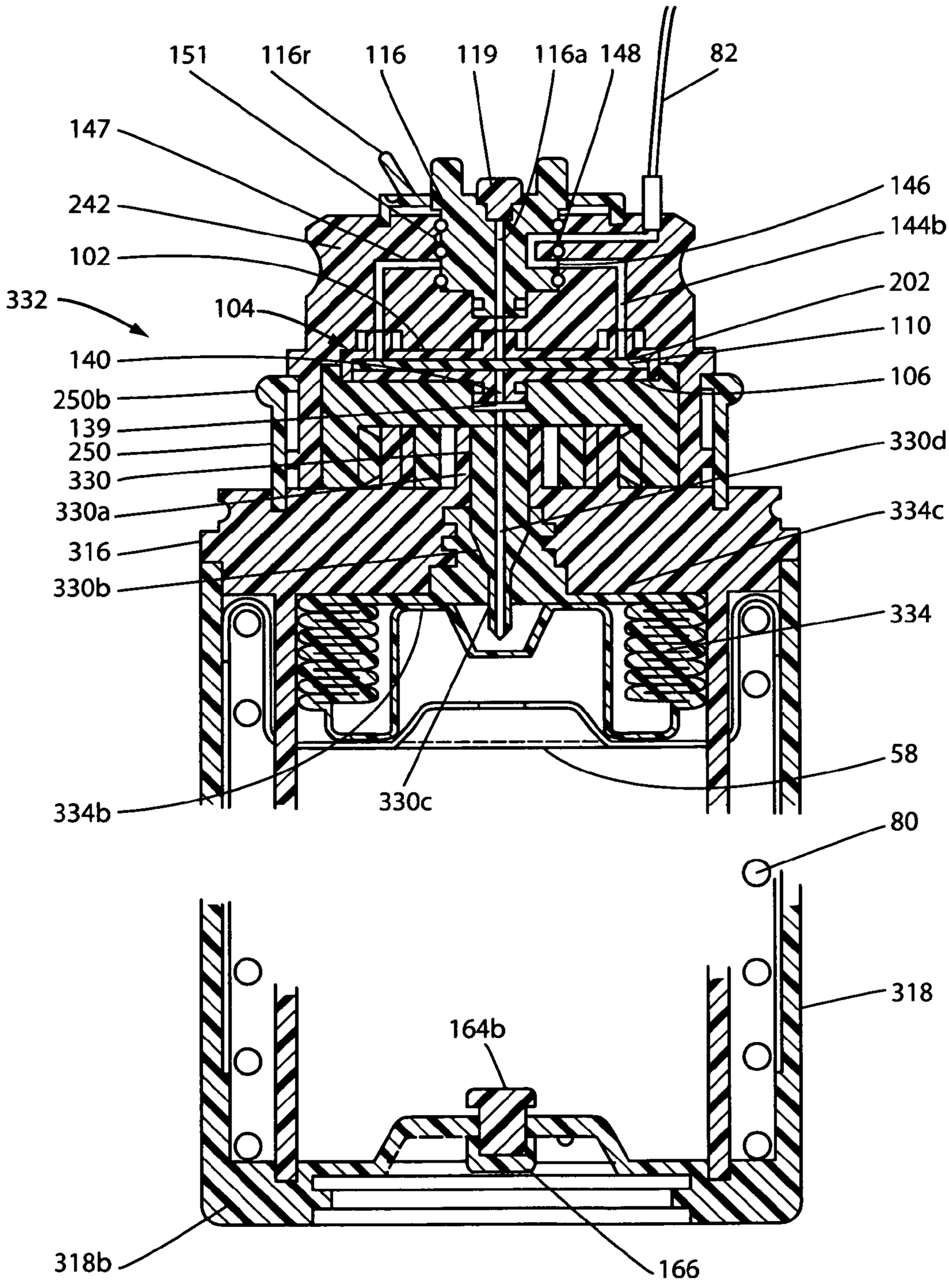
-337-
334b
58
80
164b
166
318b

FIG. 92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144b
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106
330d
334c
334
58
80
318
164b
318b
166

FIG. 93

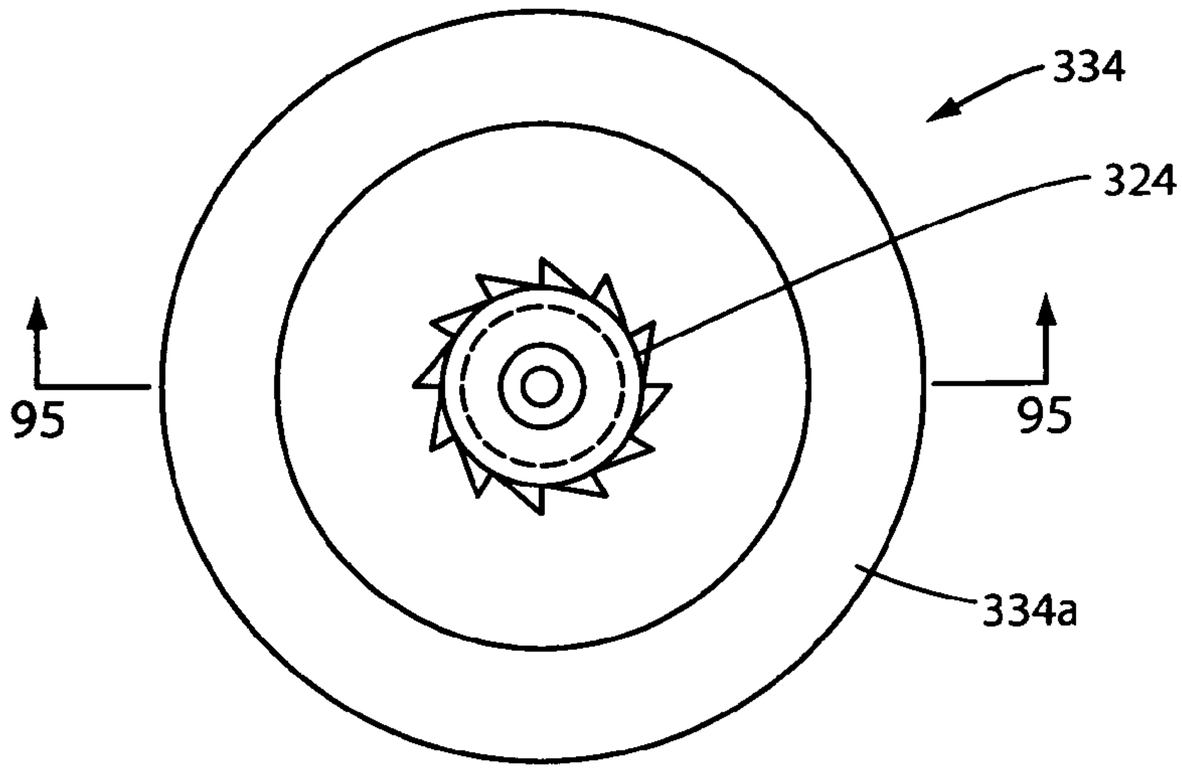


FIG. 94

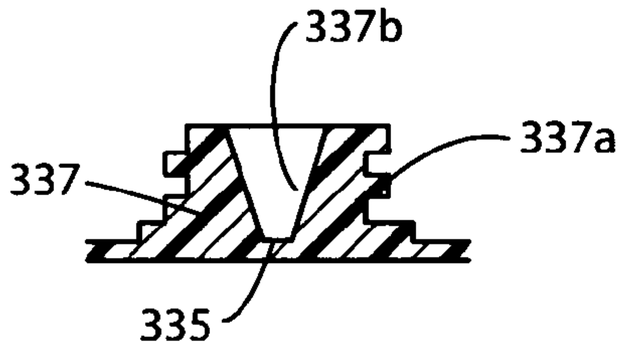
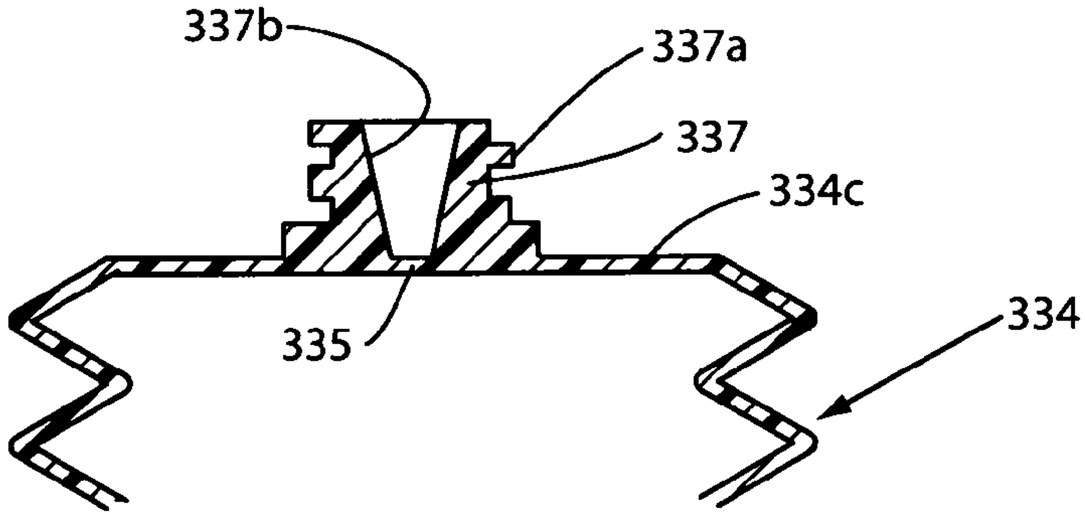


FIG. 96



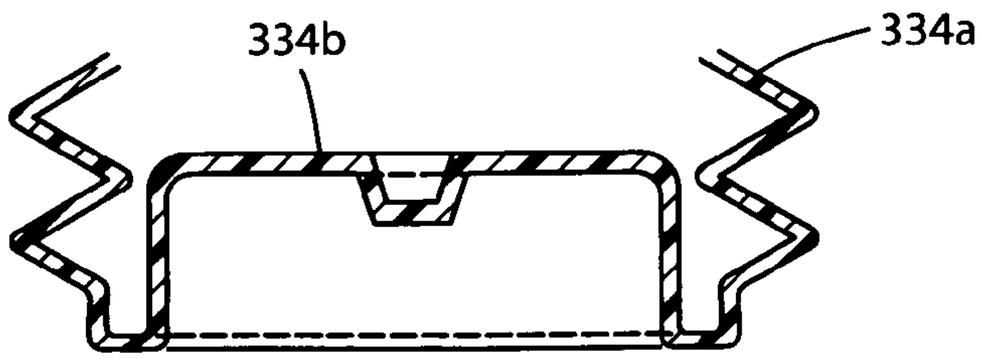
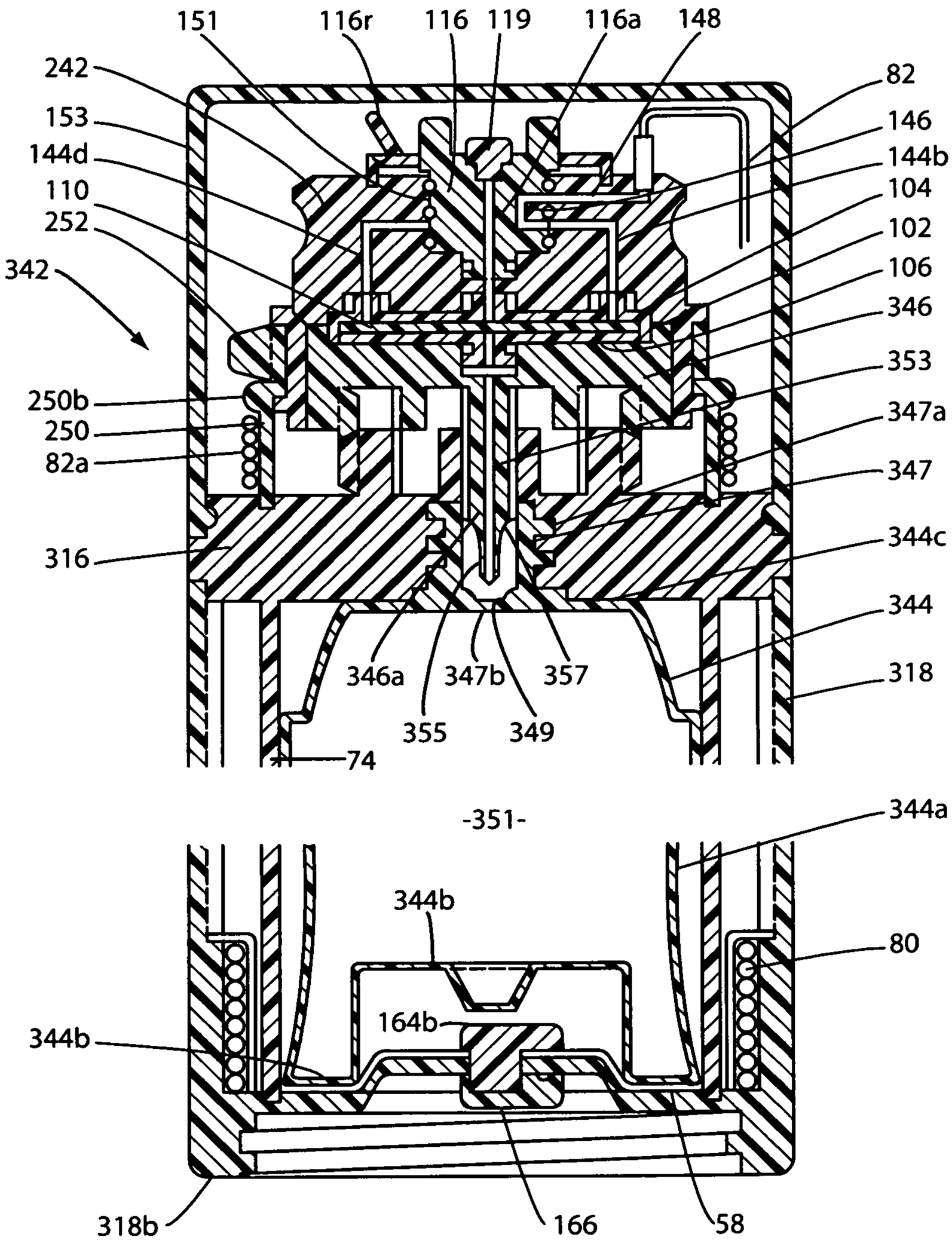


FIG. 95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144b
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347a
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344c
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-351-
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164b
344b
318b
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FIG. 97

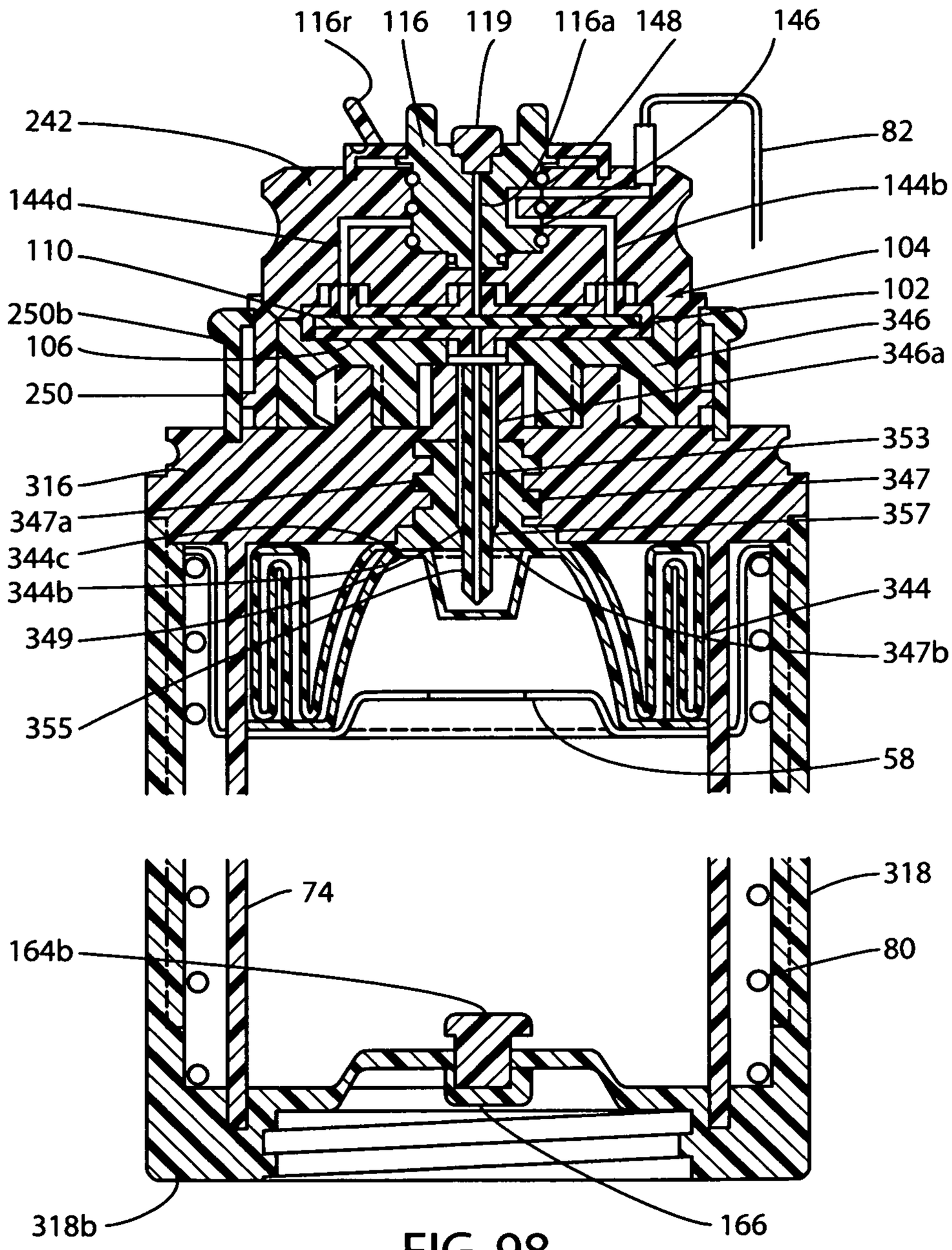
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FIG. 98

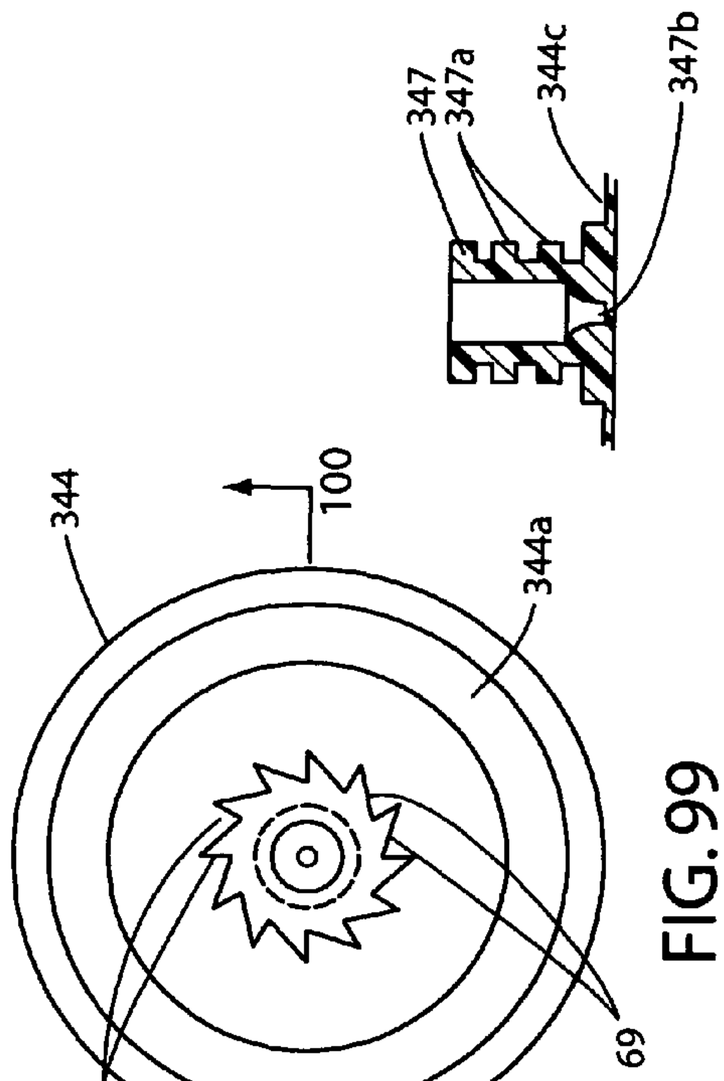


FIG. 99

FIG. 101

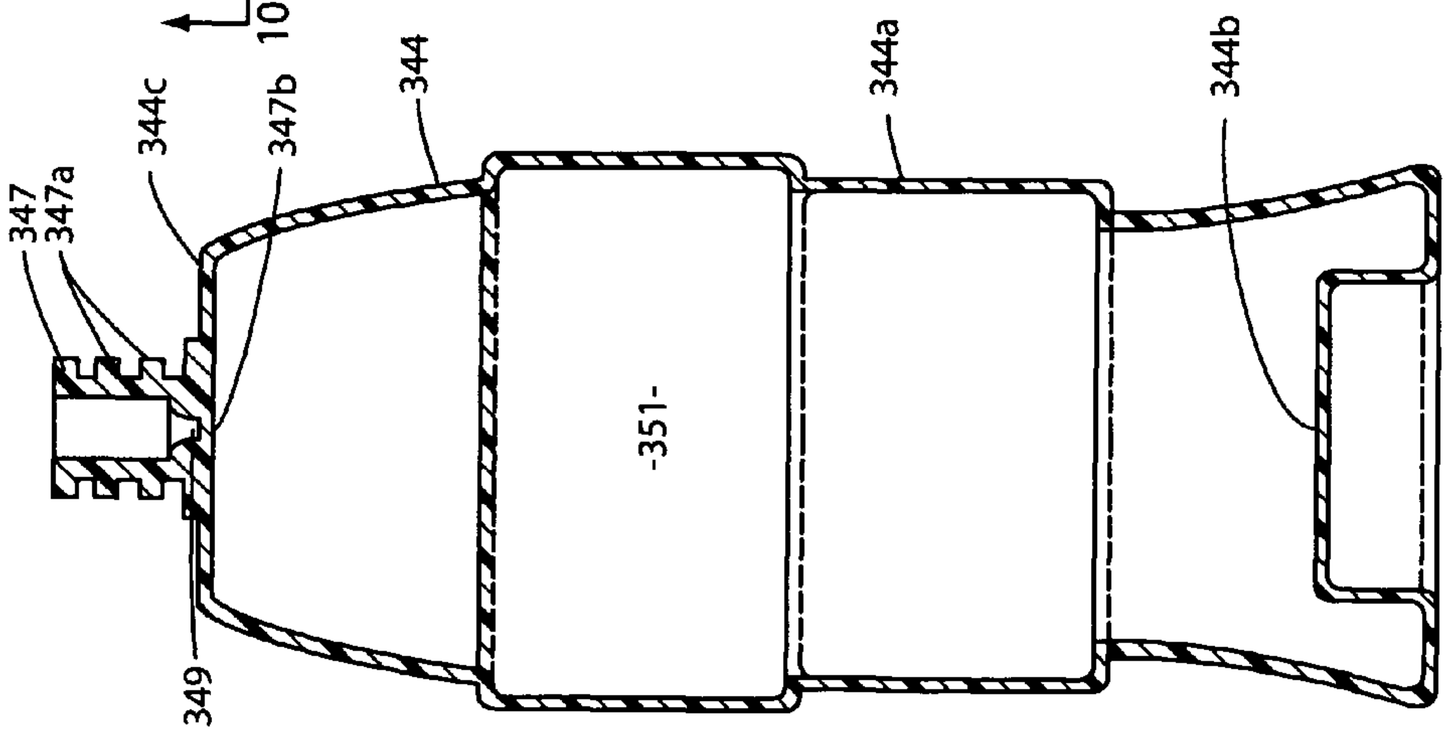
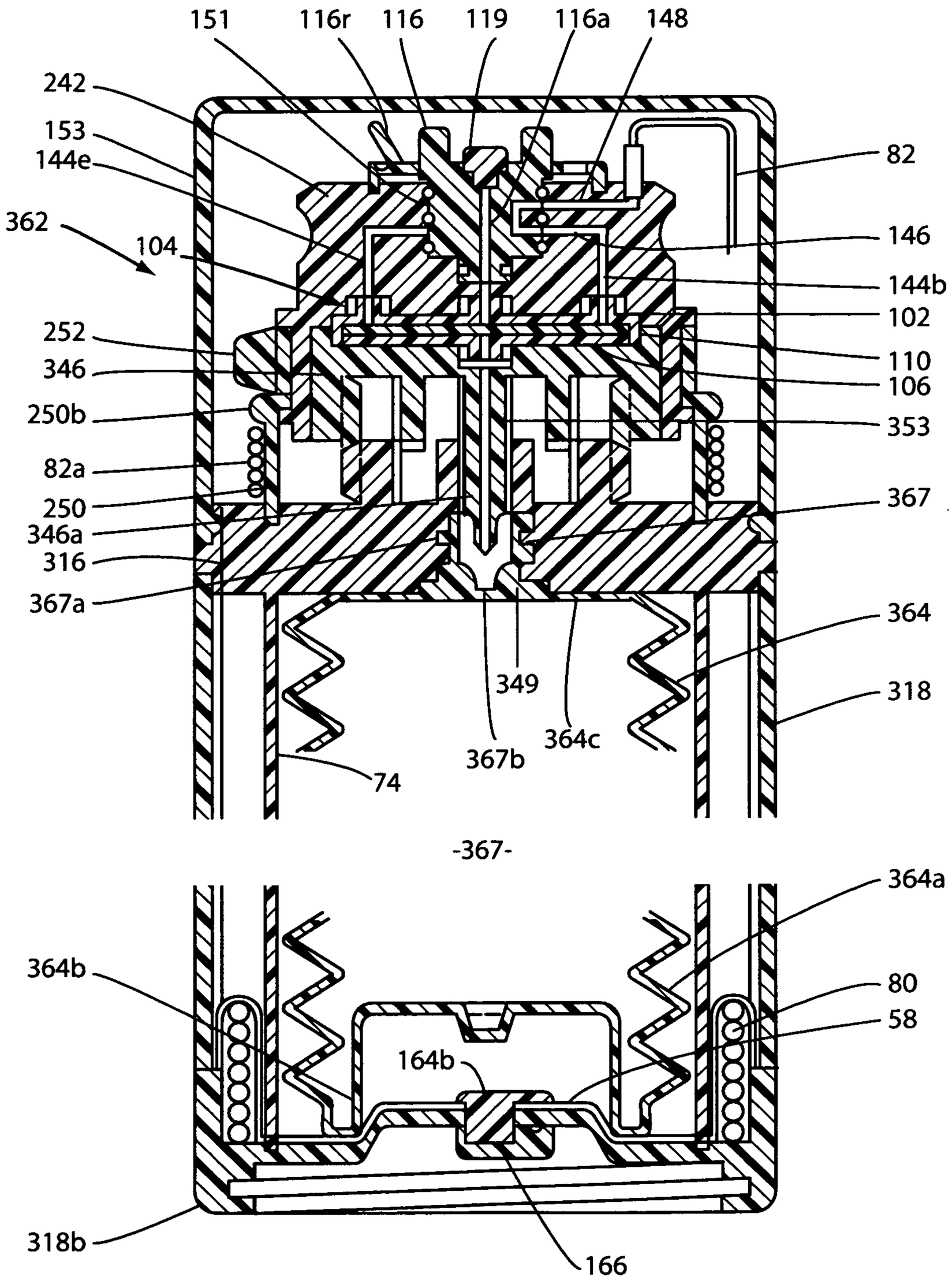


FIG. 100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144b
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250b
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82a
367
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367a
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318
364c
367b
74
364a
364b
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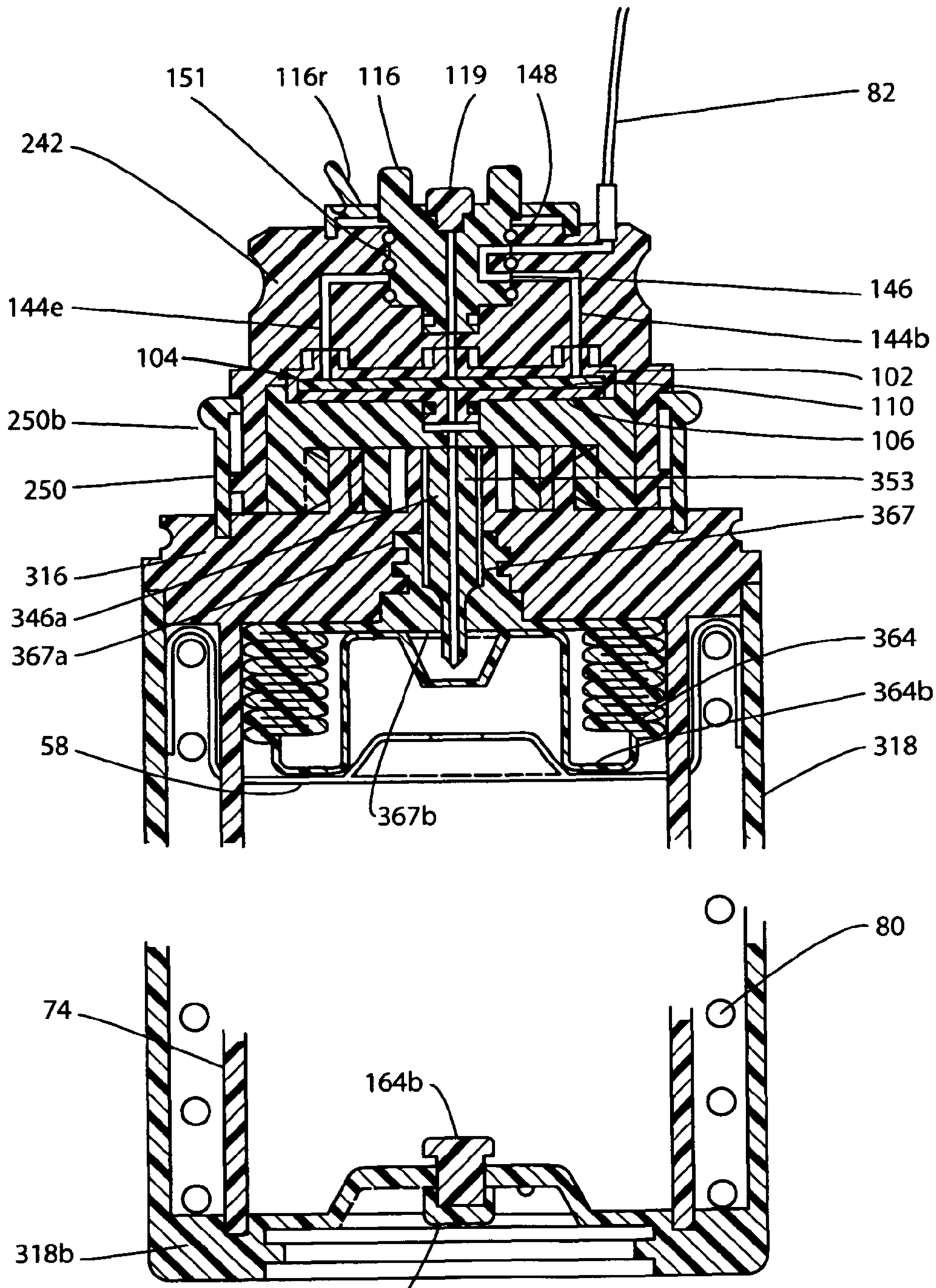
164b
318b
166

FIG. 102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367a
364b
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367b
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318b
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FIG. 103

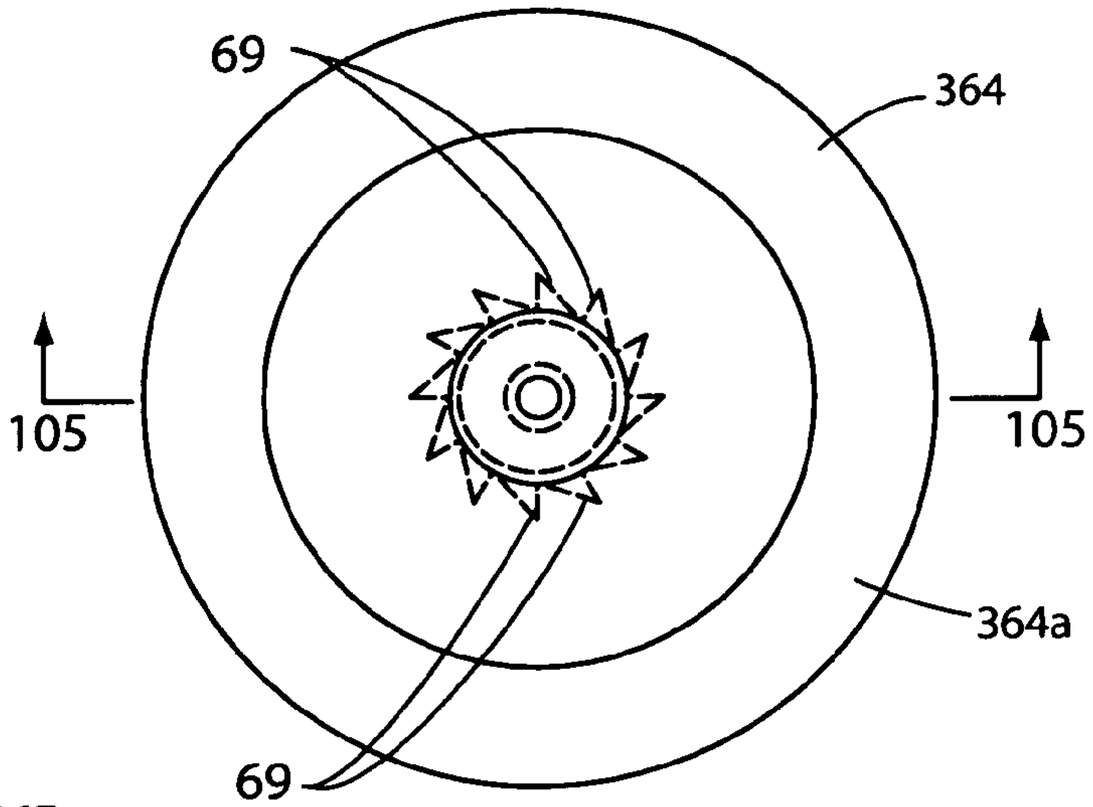


FIG. 104

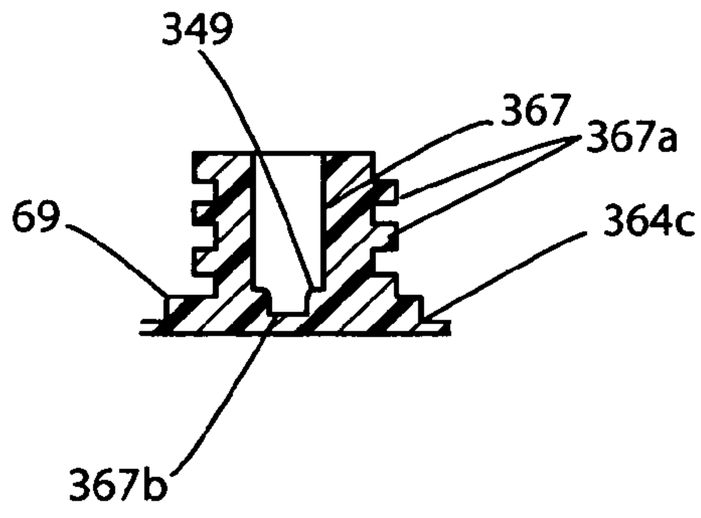
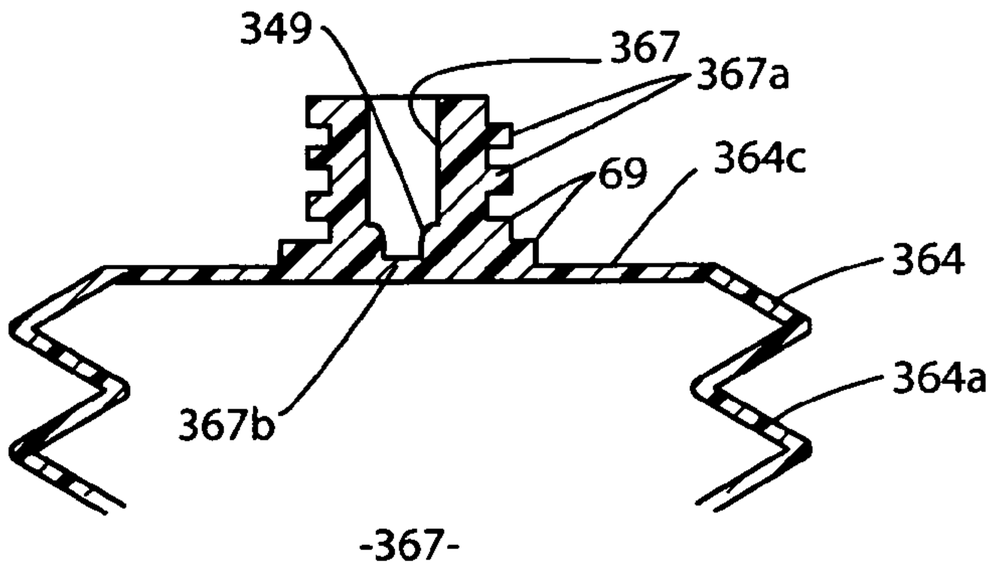


FIG. 106



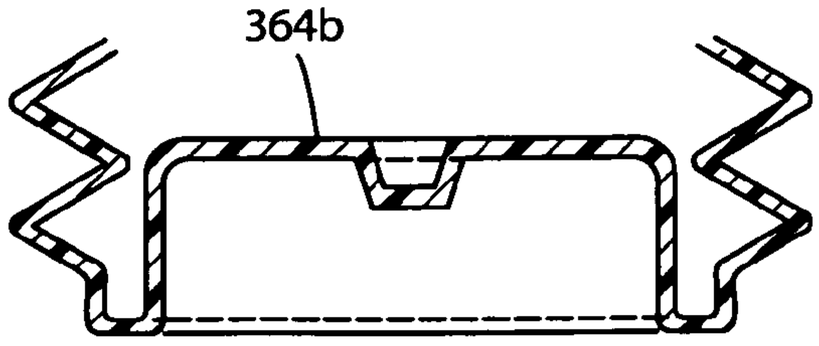
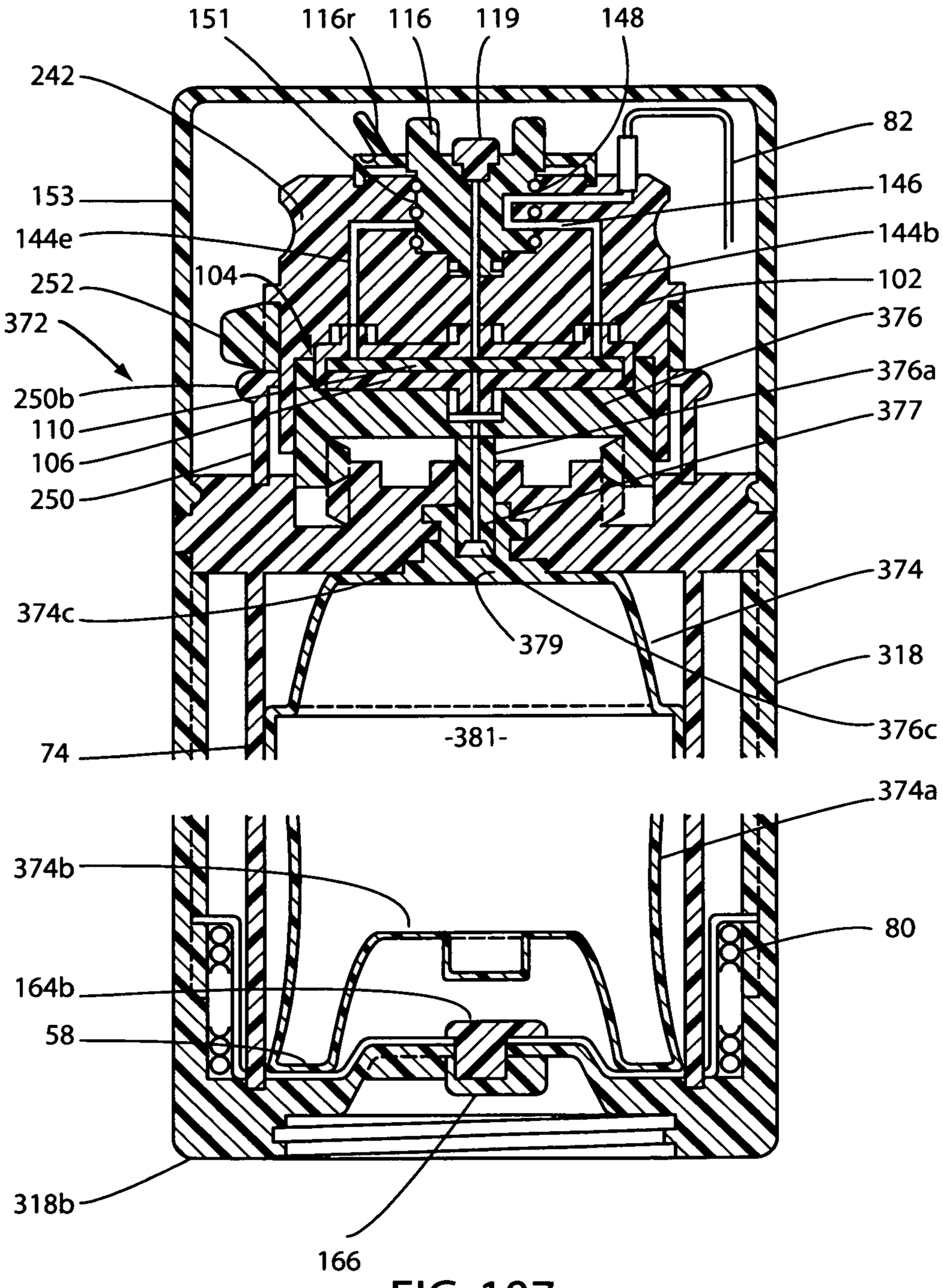


FIG. 105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110
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374a
374b
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164b
58
318b
166

FIG. 107

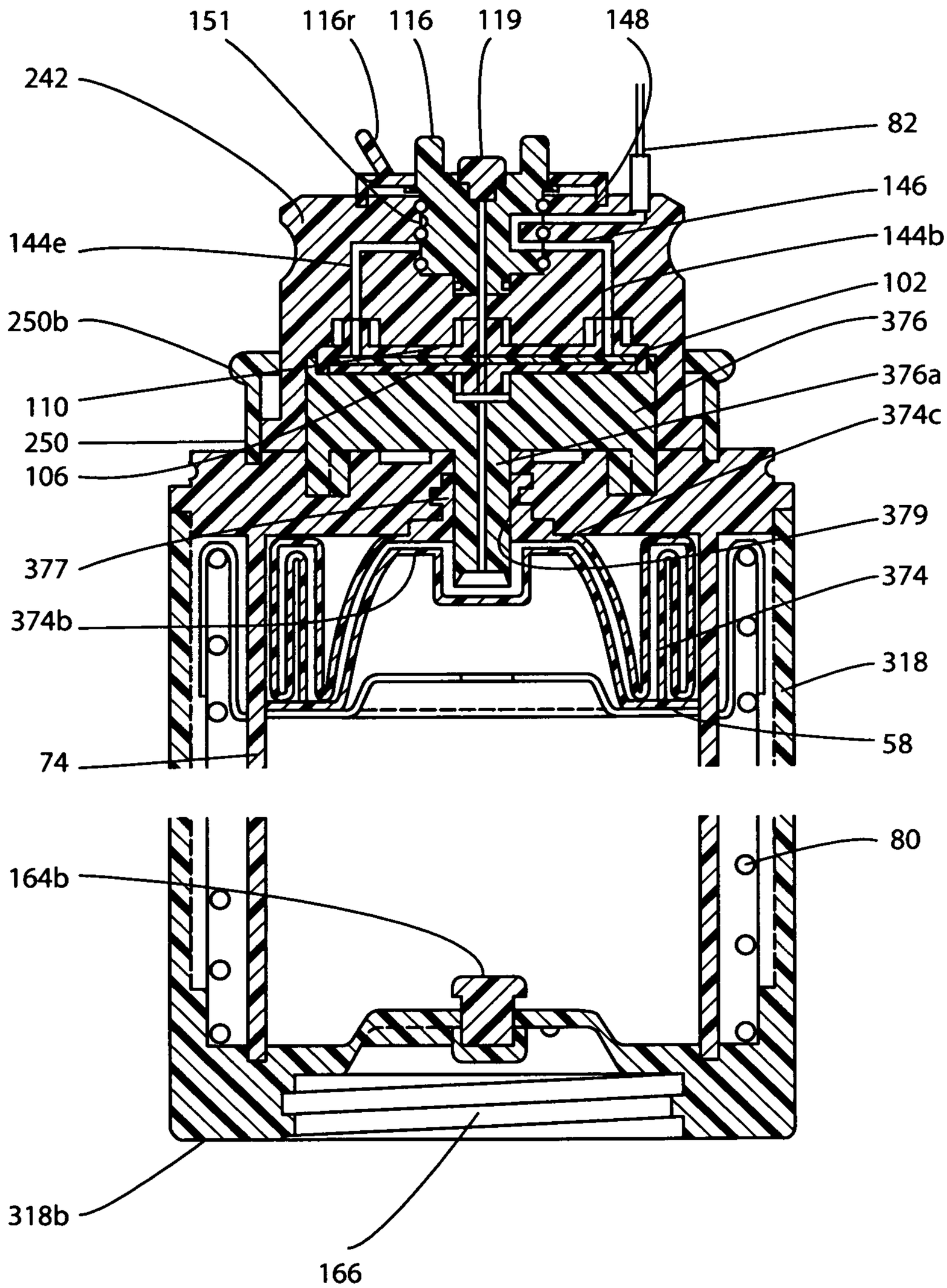
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FIG. 108

FIG. 109

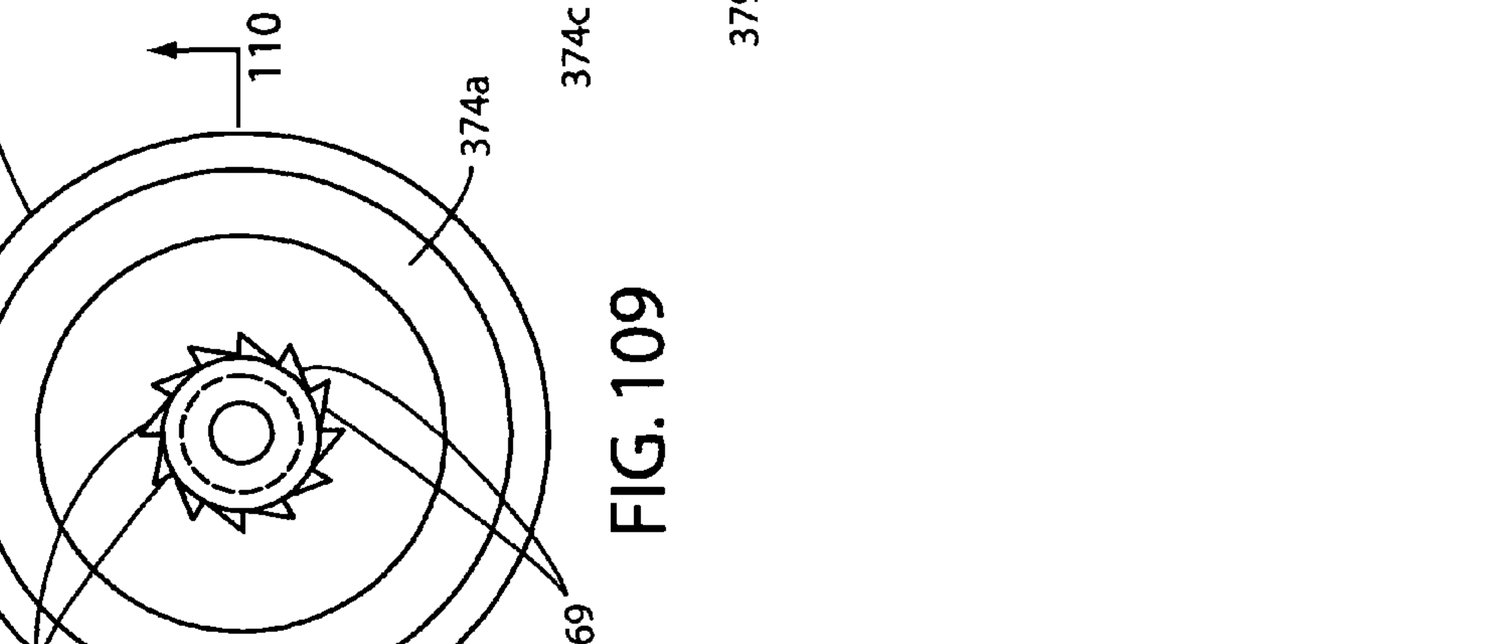
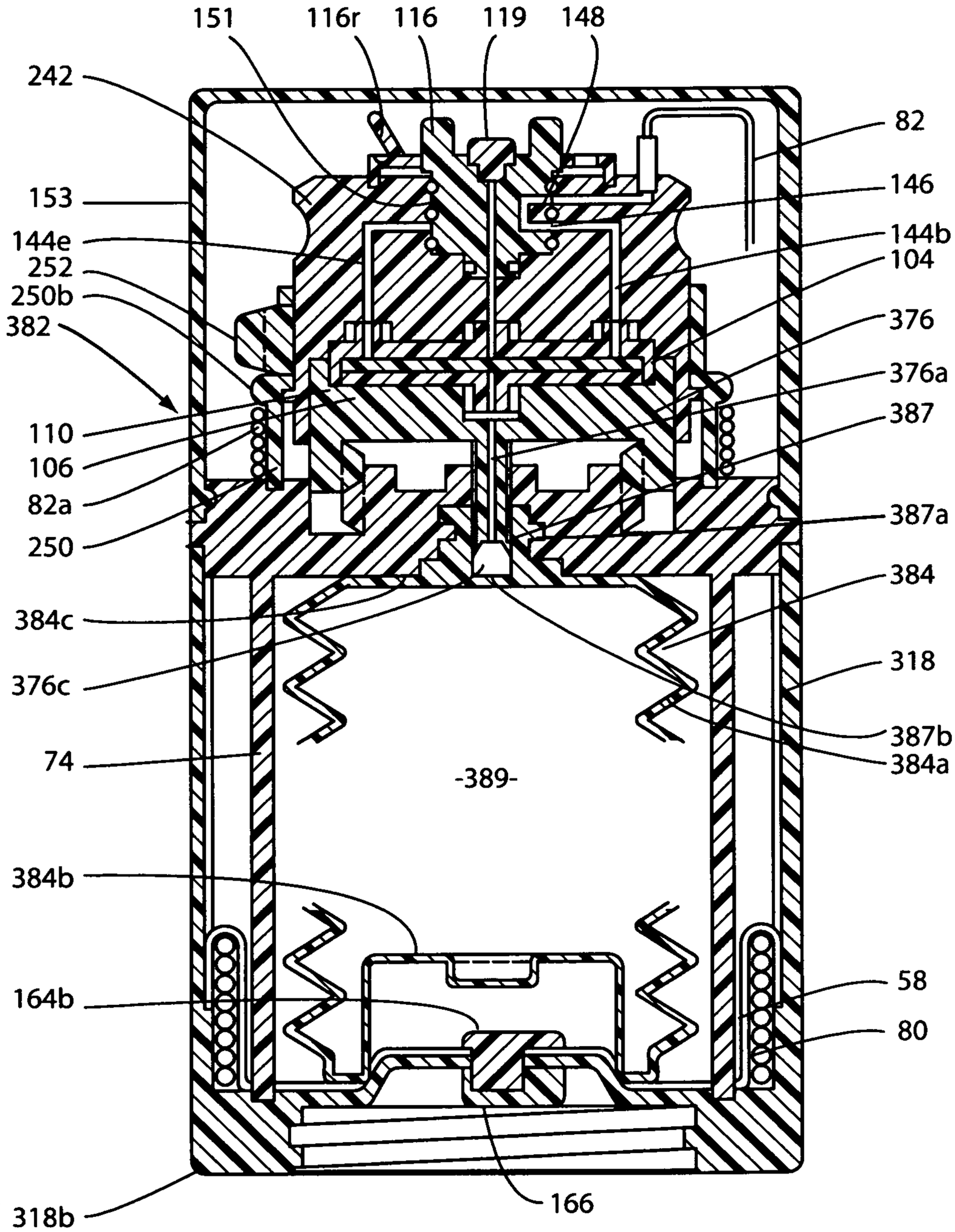


FIG. 110

FIG. 111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250b
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82a
387a
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376c
387b
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384a
-389-
384b
164b
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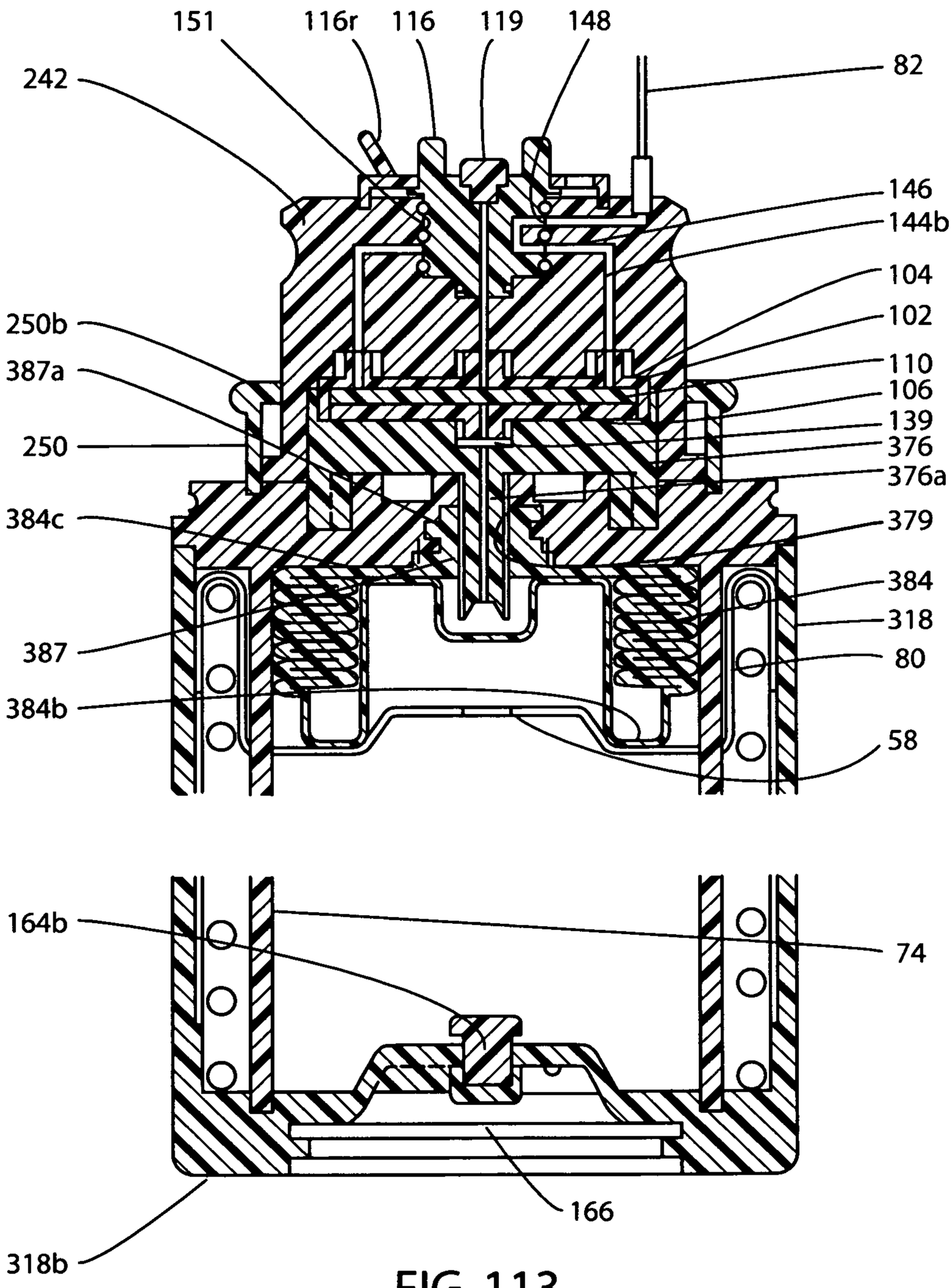
80
166
318b

FIG. 112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250b
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384b
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164b
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166
318b

FIG. 113

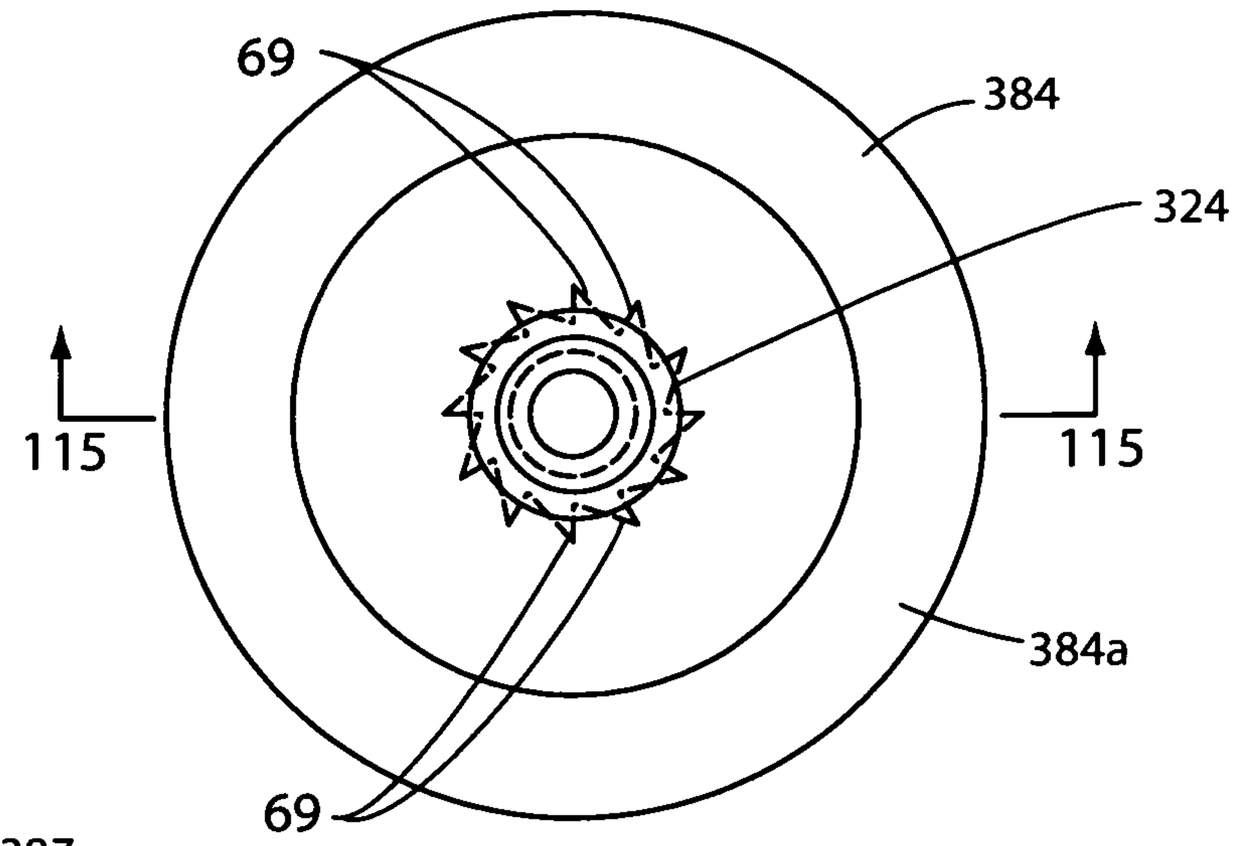


FIG. 114

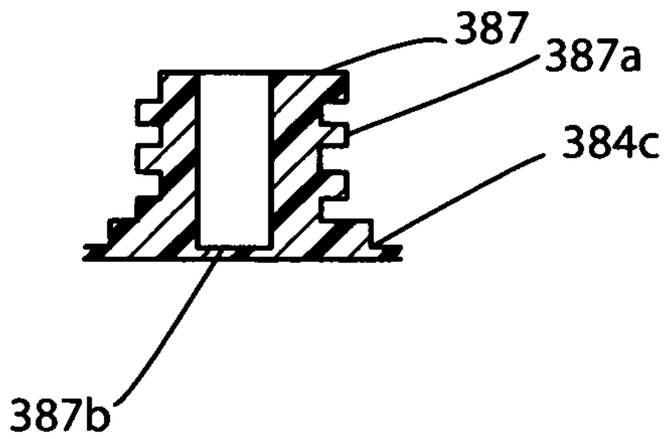
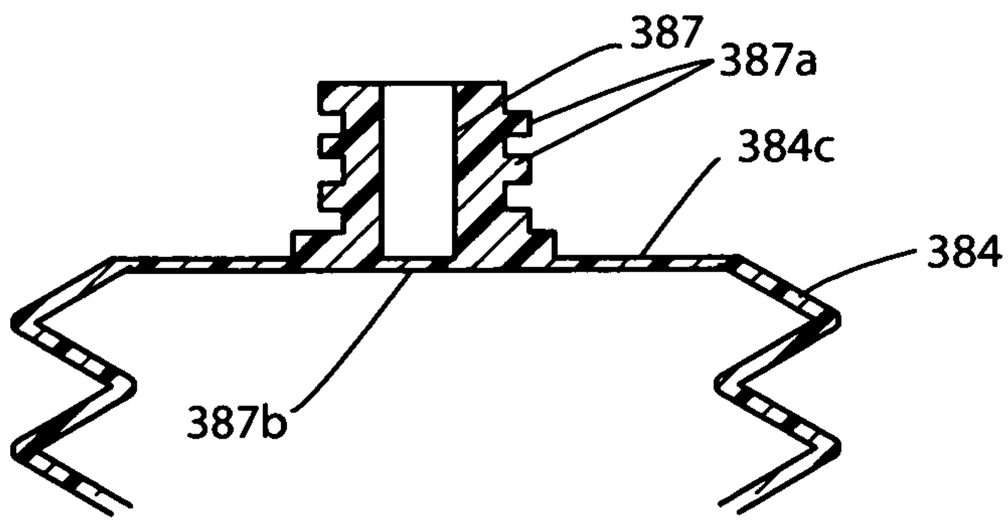


FIG. 116



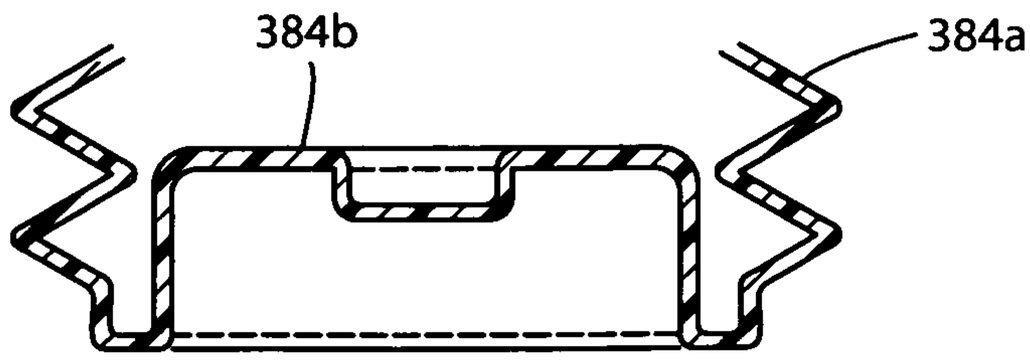
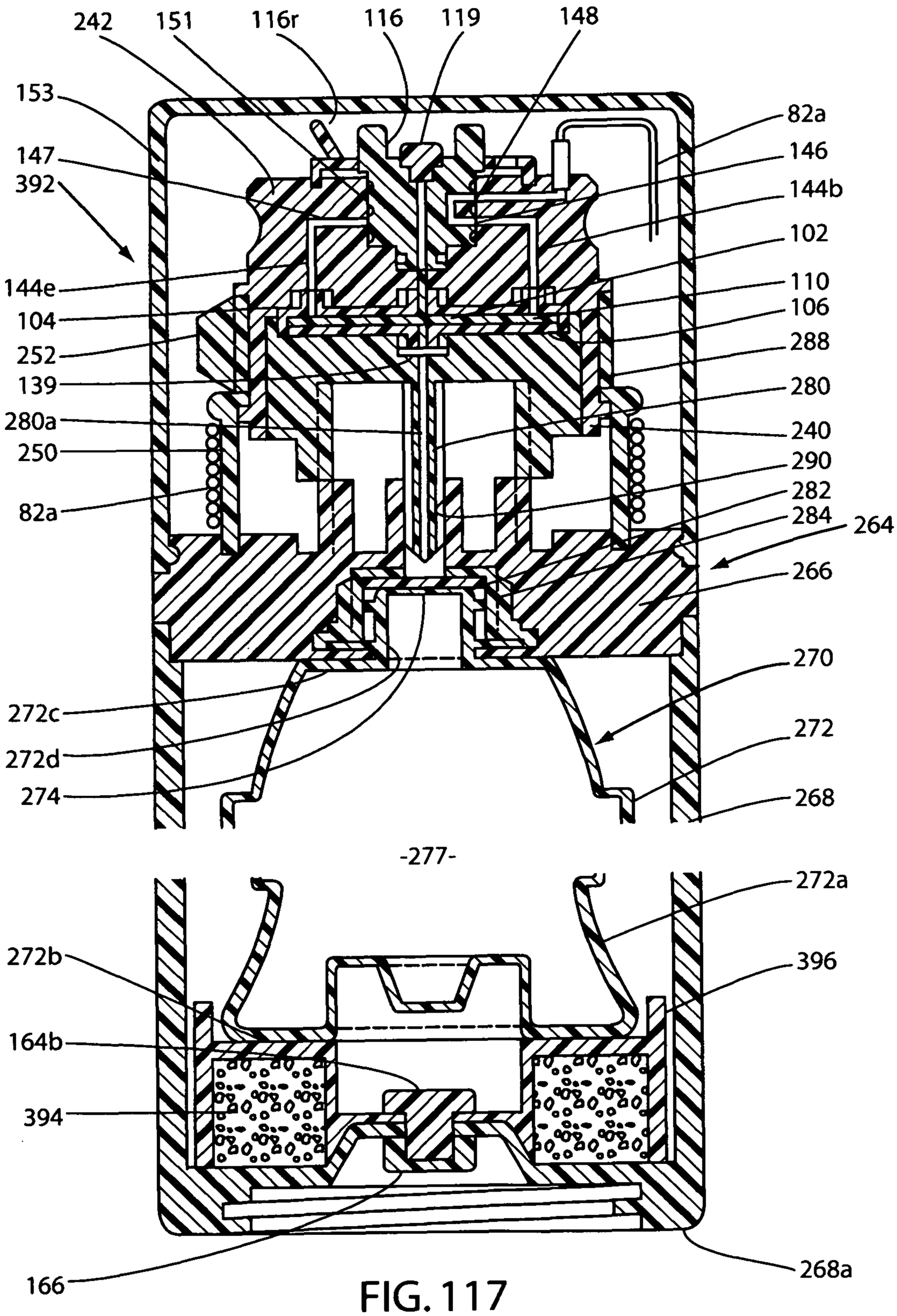


FIG. 115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82a
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270
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272c
272d
274
272a
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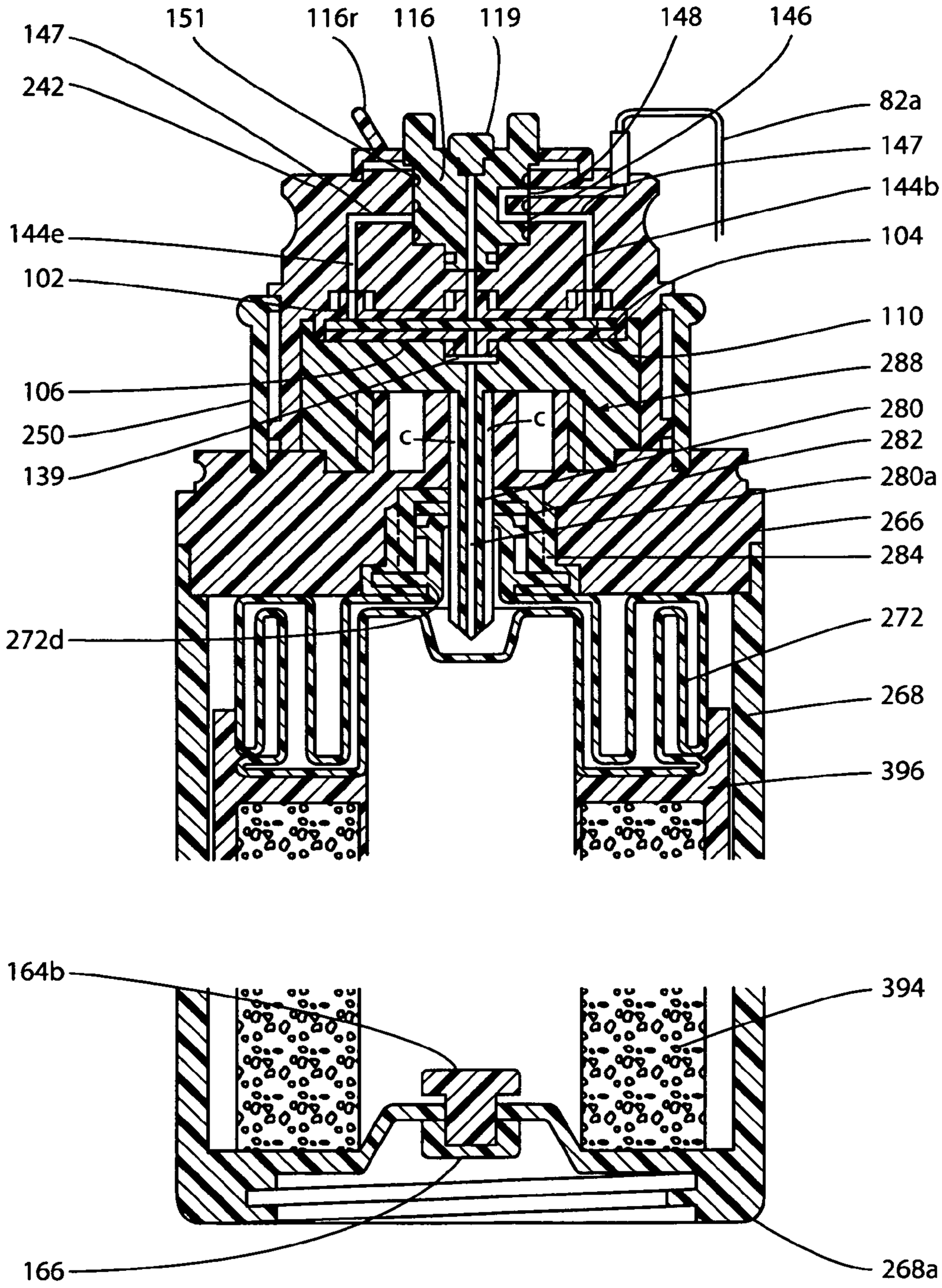
272b
164b
394
166
268a

FIG. 117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116r
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280a
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272d
272
268
396
164b
394
166
268a

FIG. 118

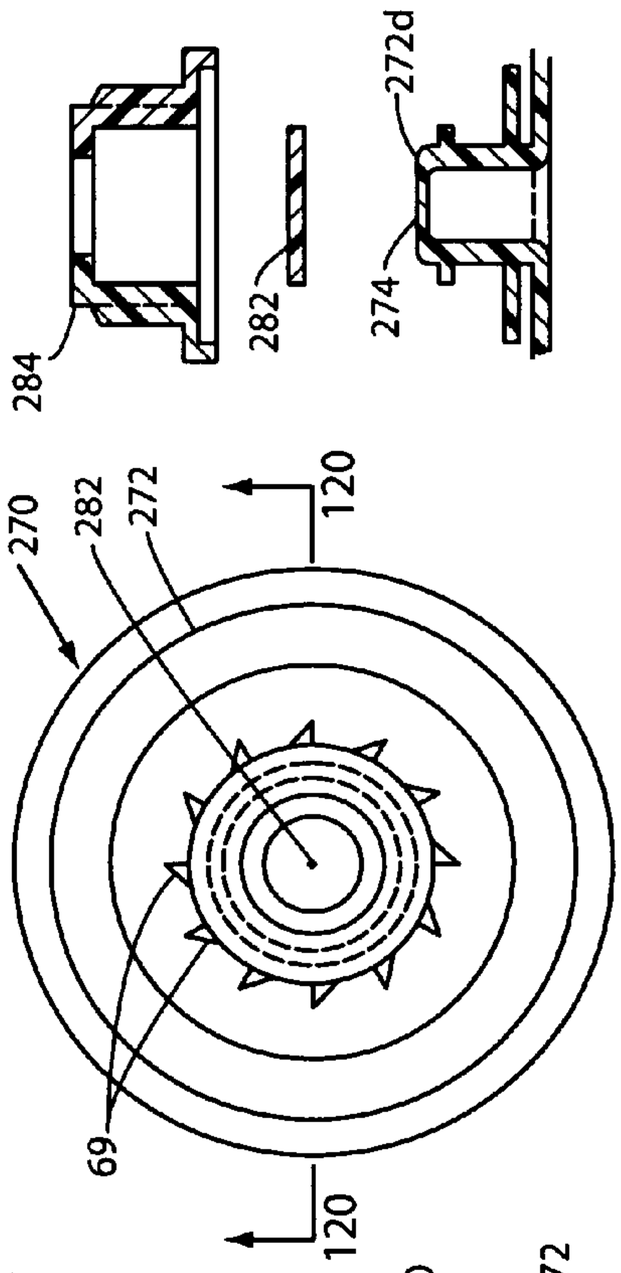


FIG. 119

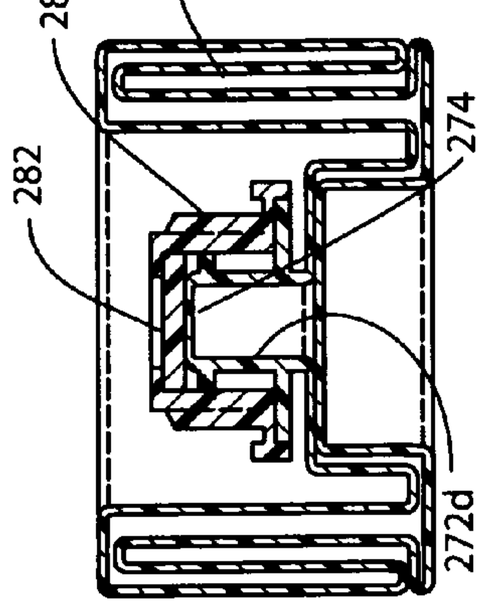


FIG. 122

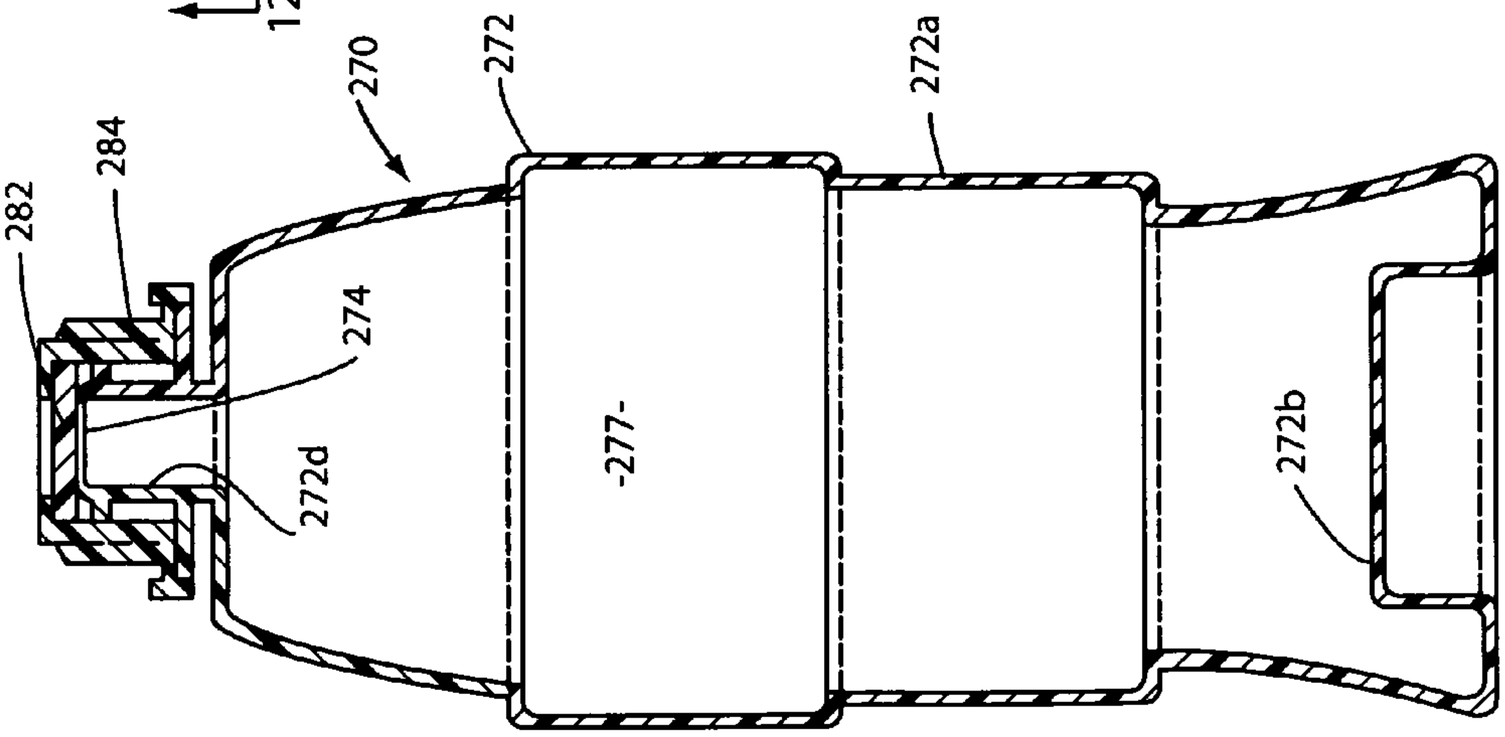
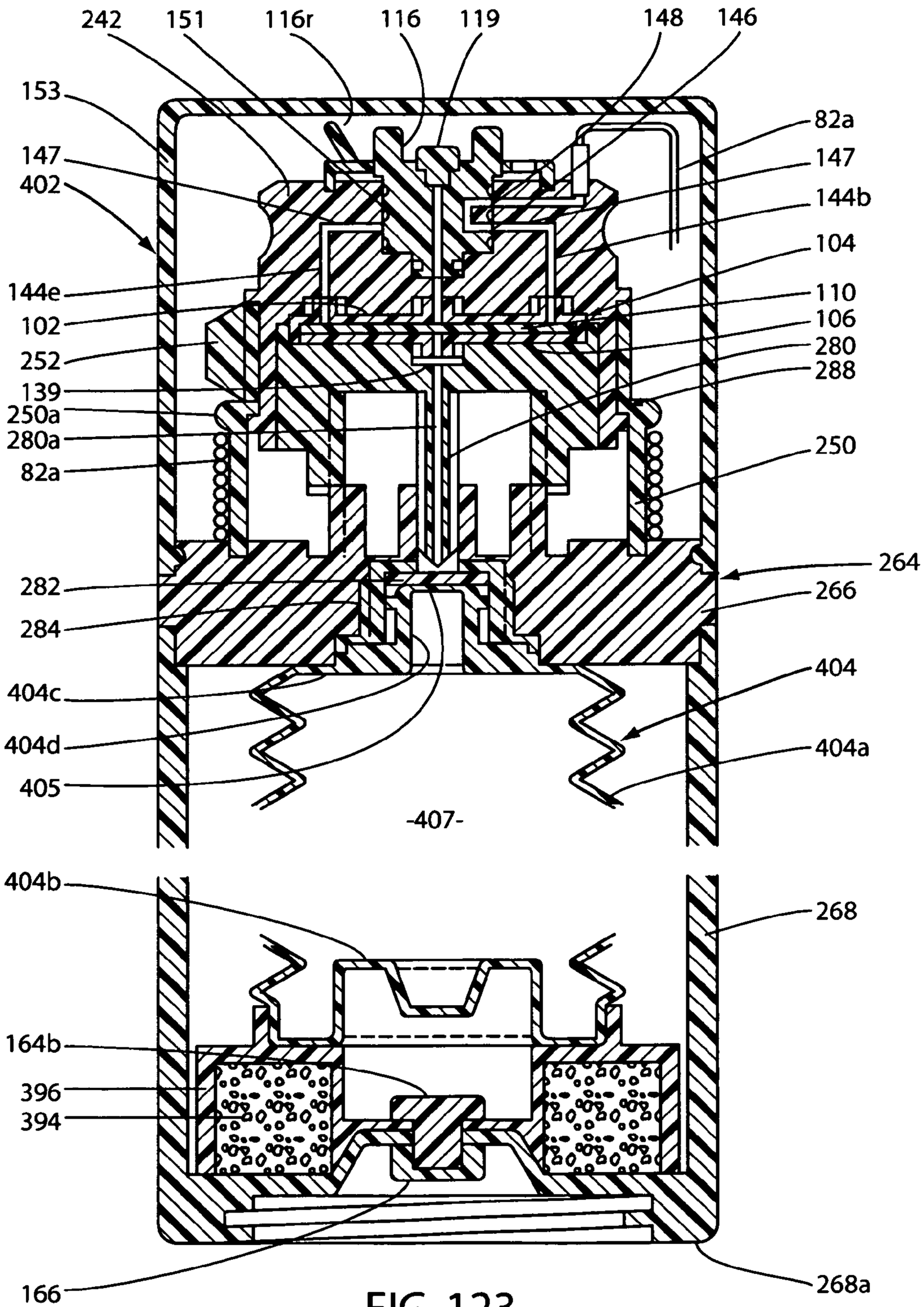


FIG. 120

FIG. 121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404c
404d
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404b
164b
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144b
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404a
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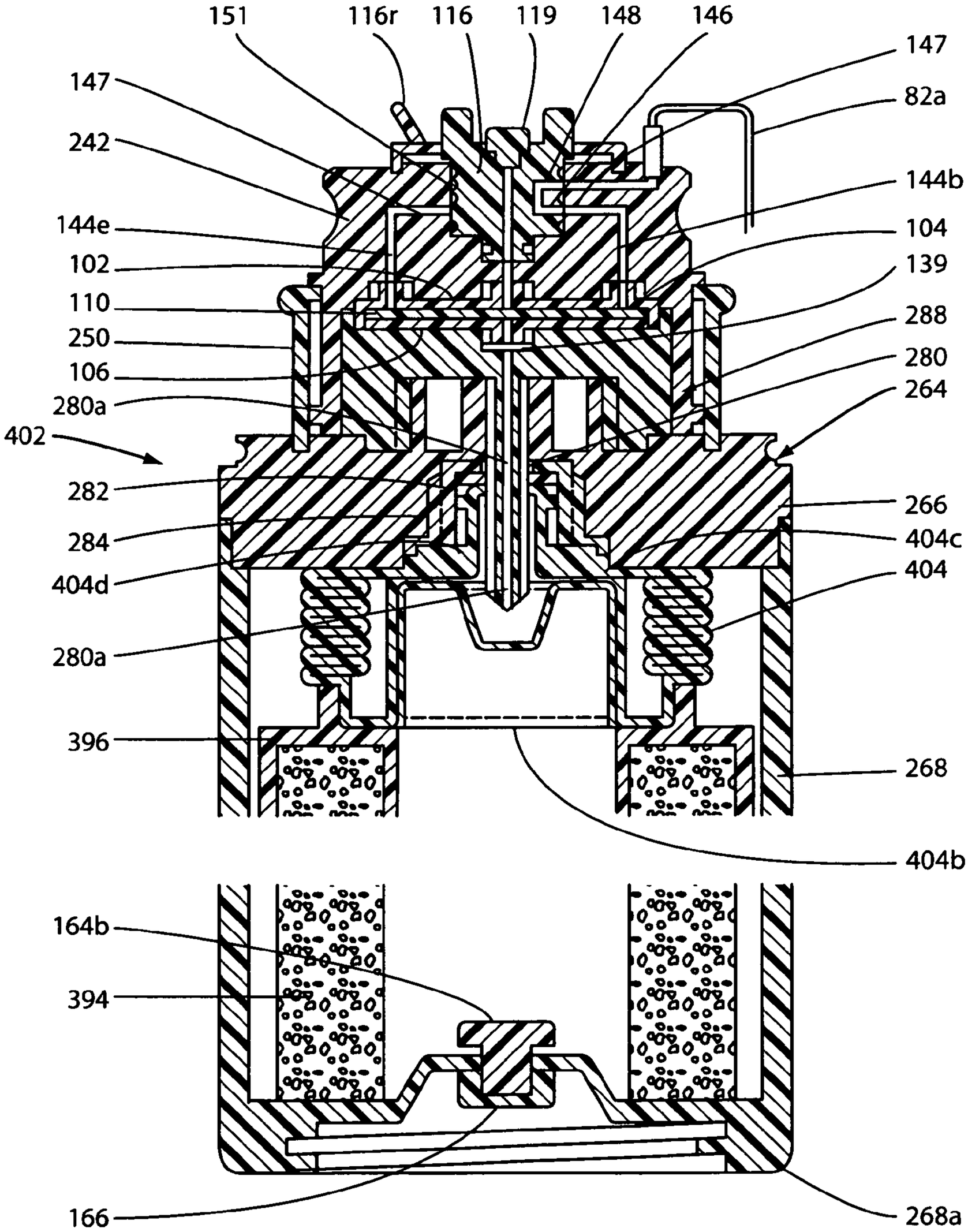
268a

FIG. 123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404c
404d
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280a
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404b
164b
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166
268a

FIG. 124

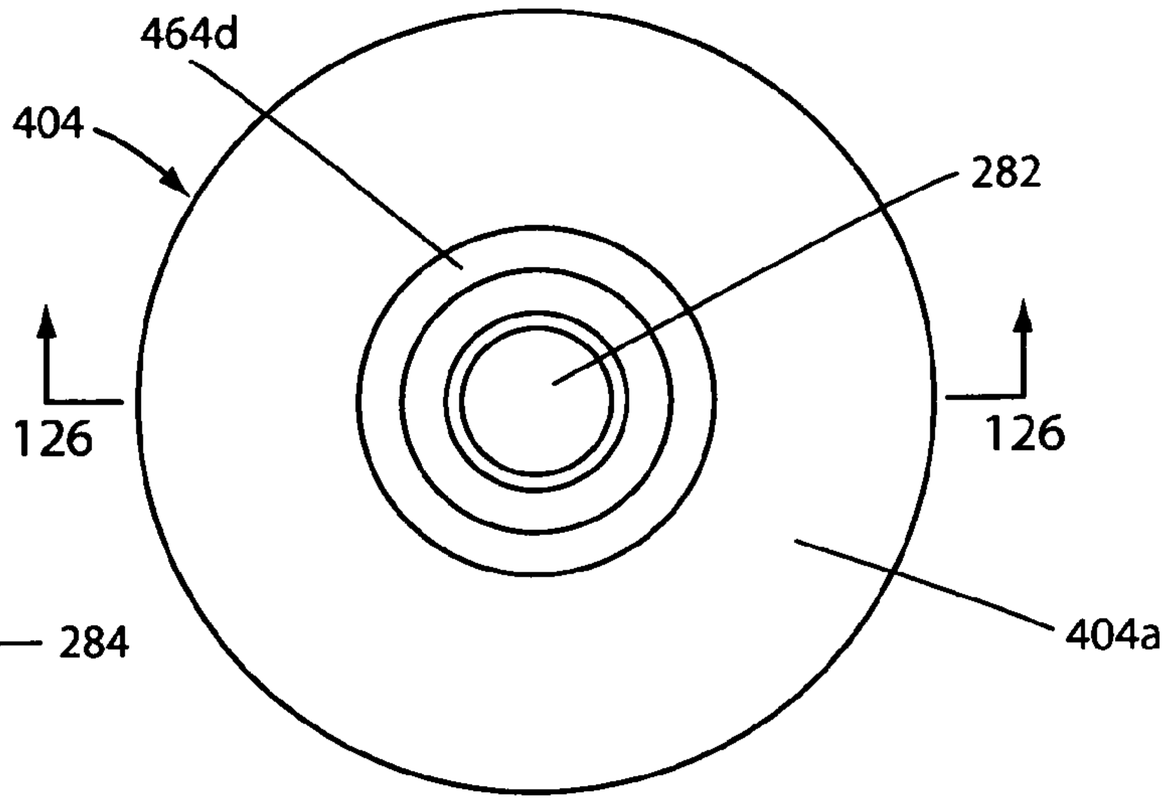

FIG. 125

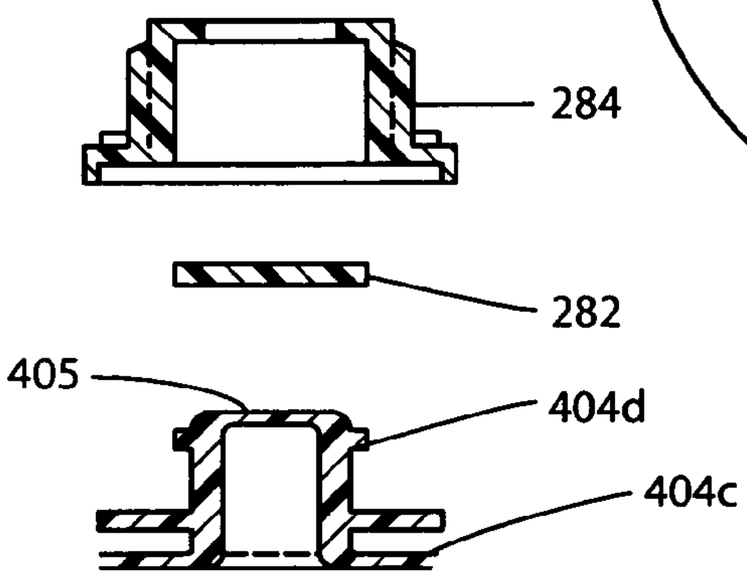

FIG. 127

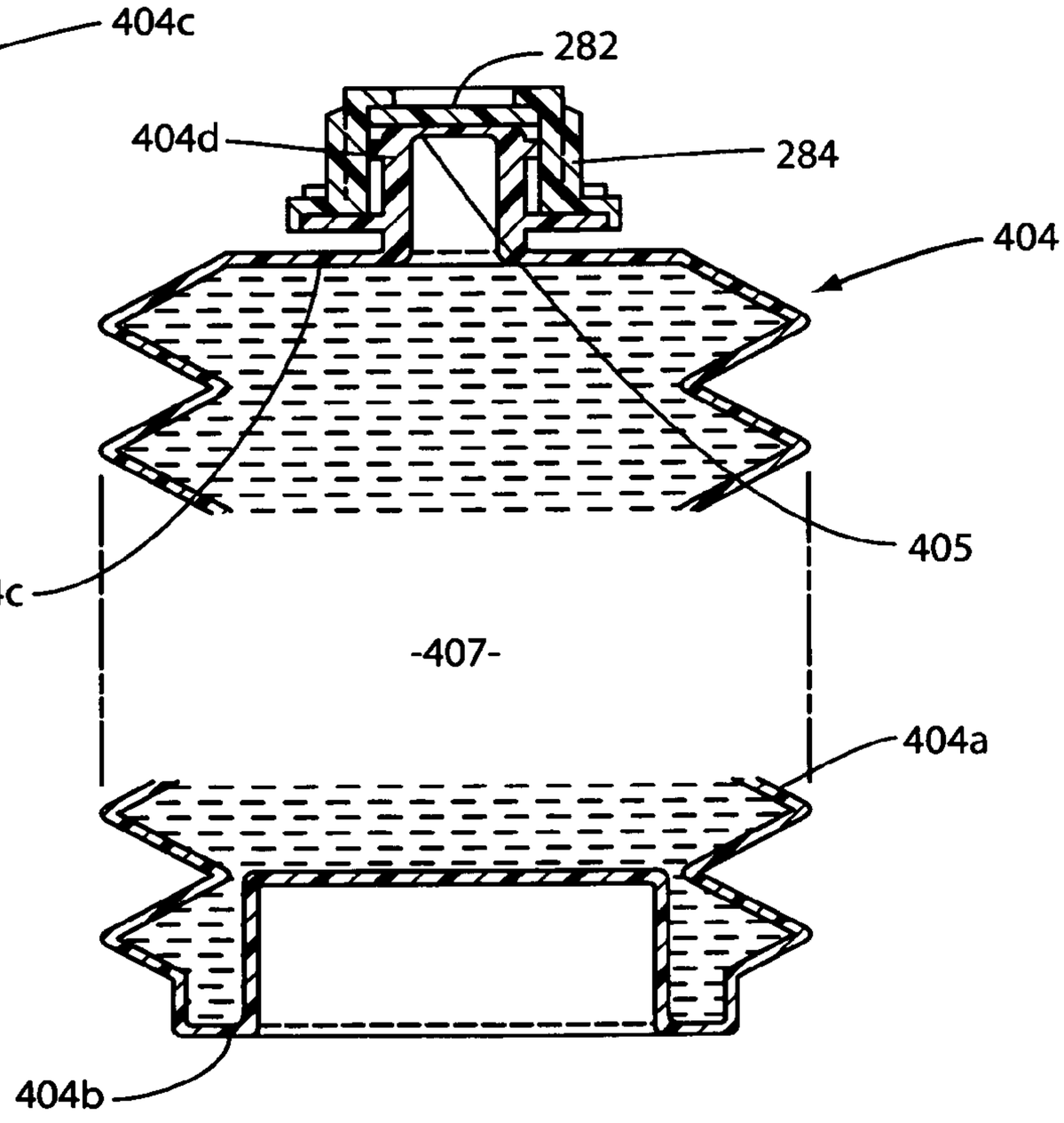

FIG. 126

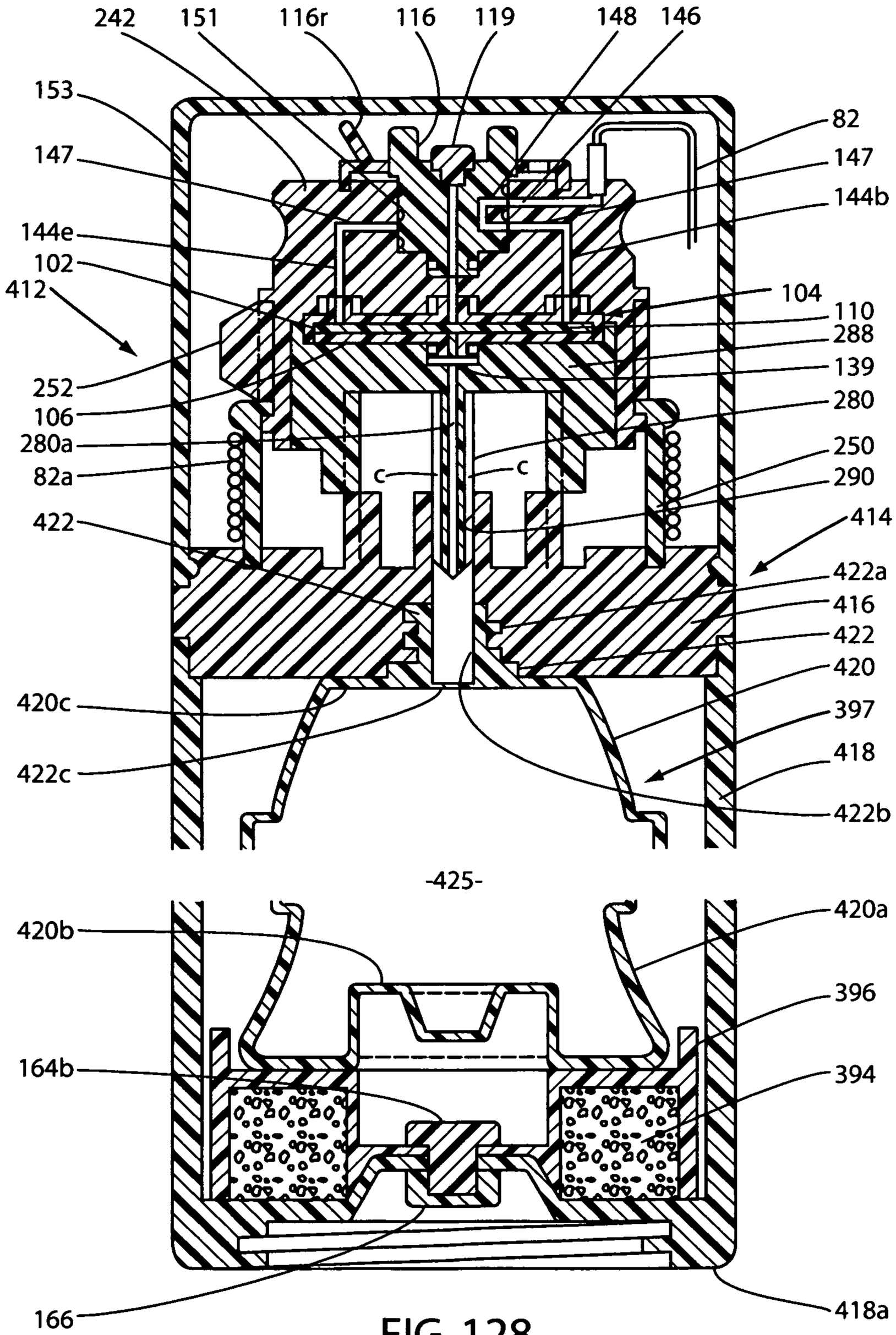
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FIG. 128

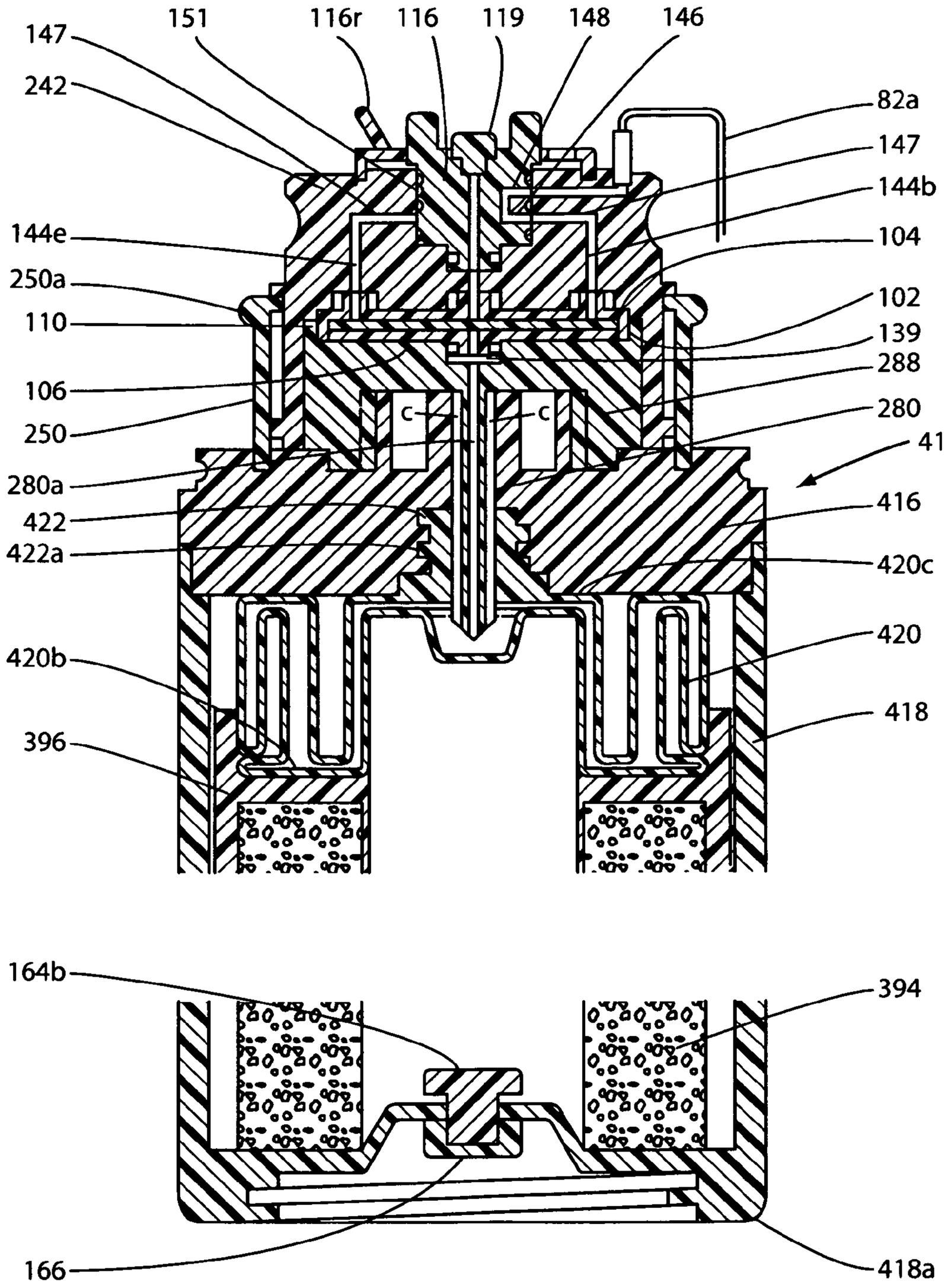
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FIG. 129

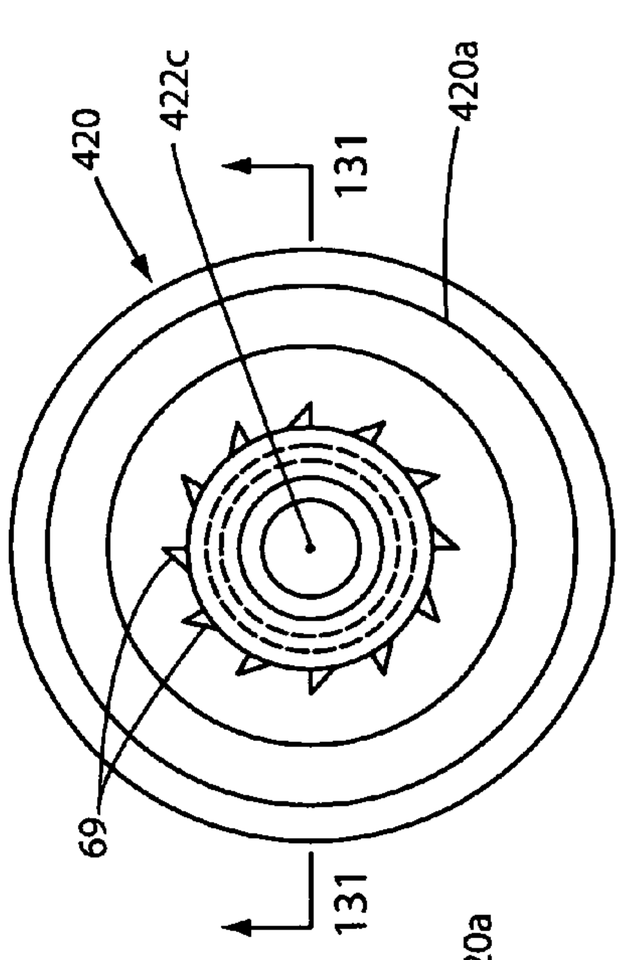

FIG. 130

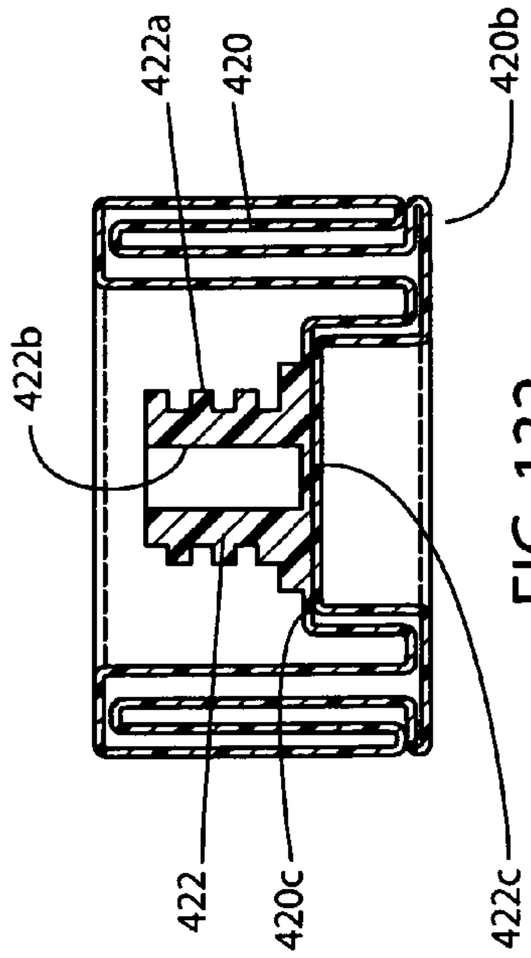

FIG. 132

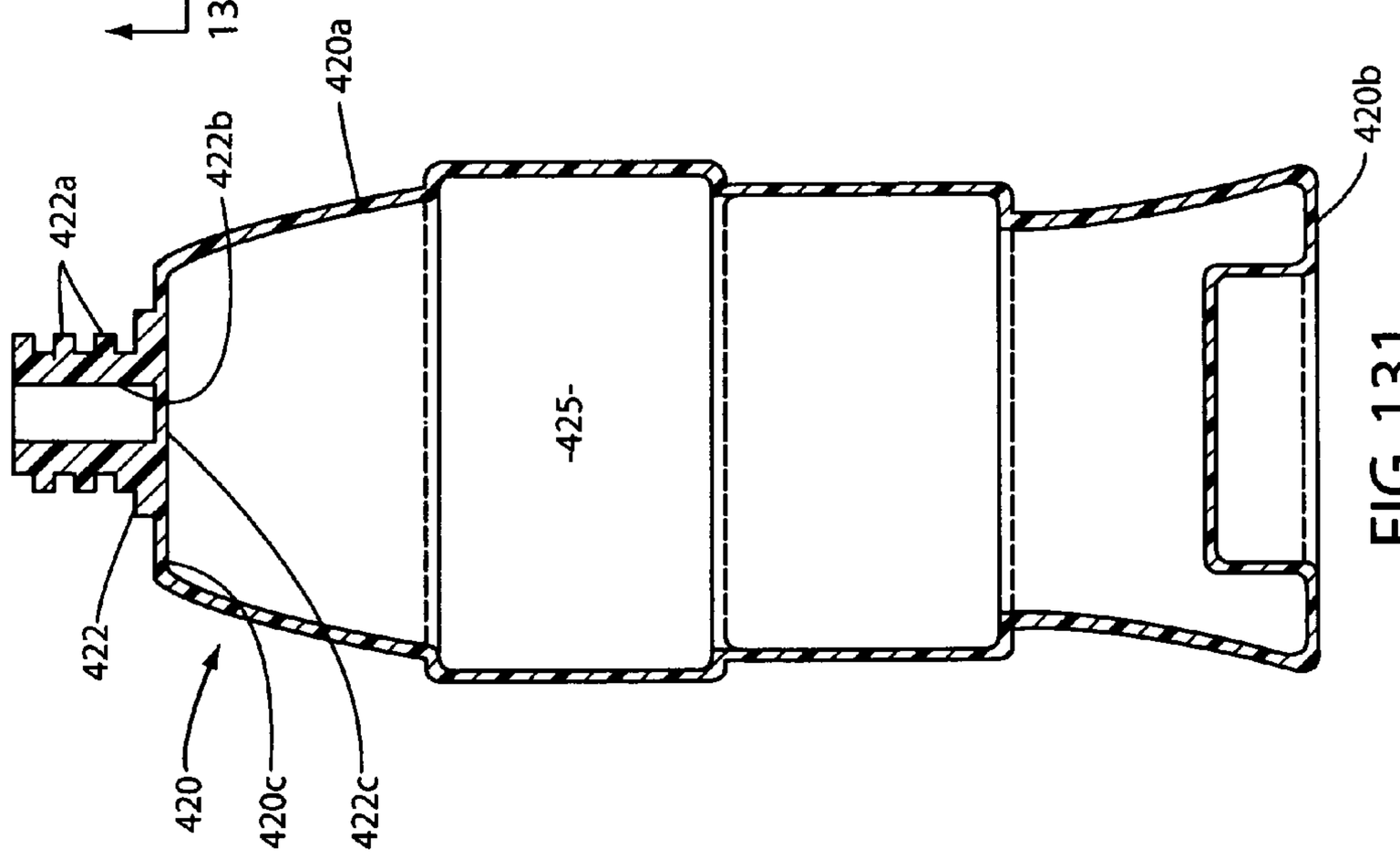

FIG. 131

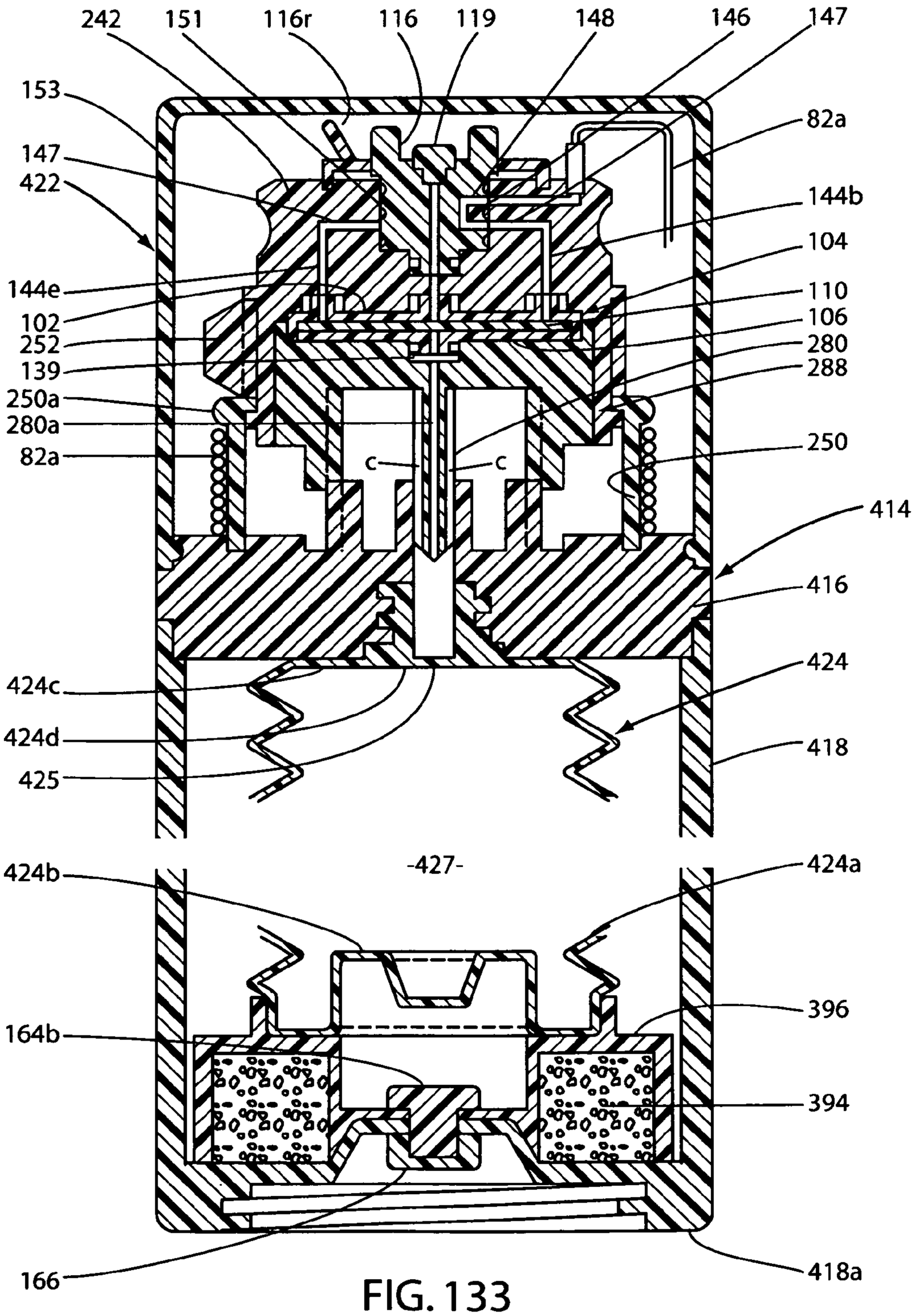
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FIG. 133

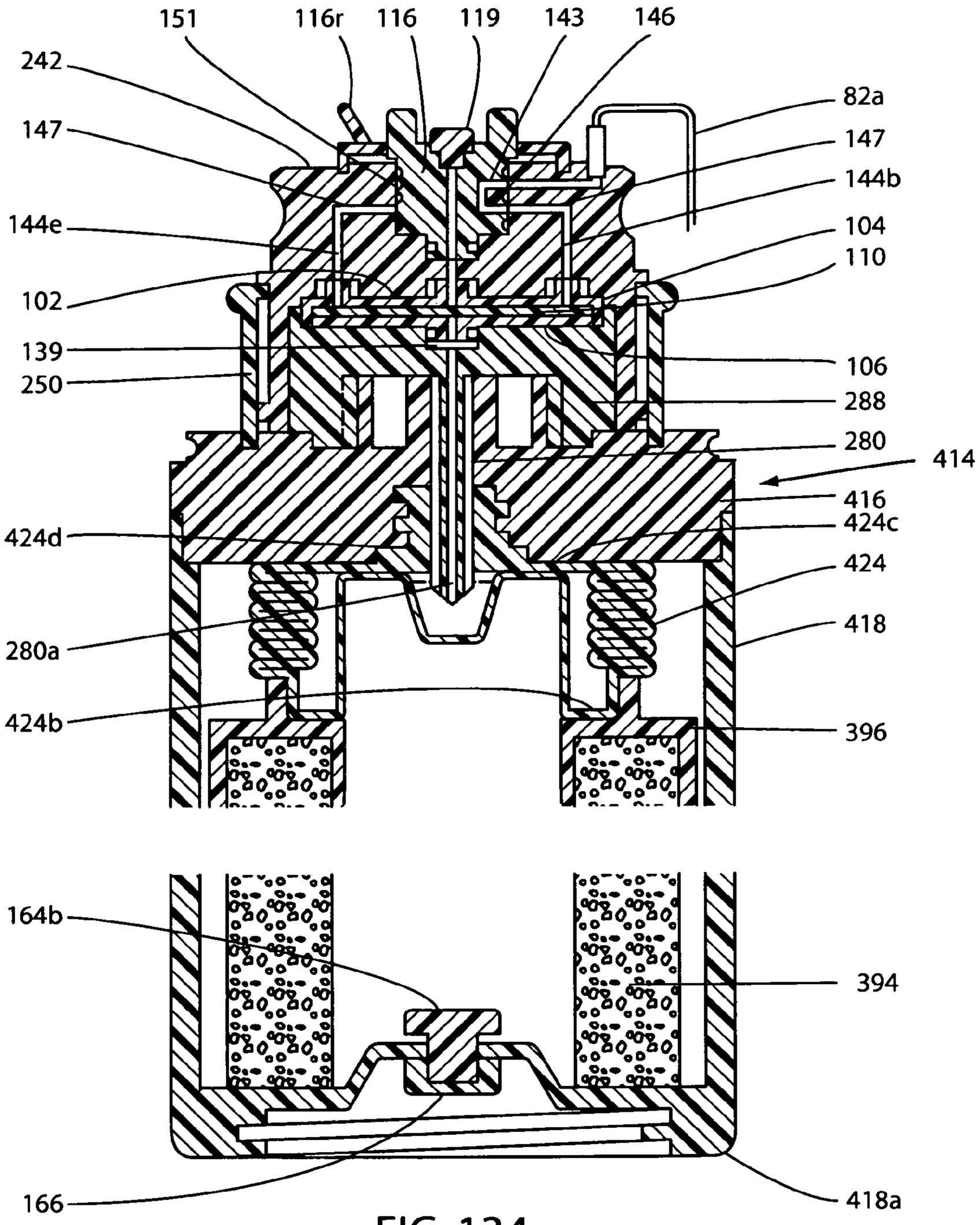
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FIG. 134

FLUID DISPENSING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This is a divisional application of application U.S. Ser. No. 11/725,222 filed Mar. 14, 2007 (now U.S. Pat. No. 7,828,772) which claimed the benefit of provisional application U.S. Ser. No. 60/783,182 filed Mar. 15, 2006.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to fluid dispensing devices. More particularly, the invention concerns medicament dispensers for dispensing medicinal fluids to ambulatory patients.

2. Description of Related Art Including Information Disclosed Under 37 CFR 1.97 and 1.98

A number of different types of medicament dispensers for dispensing medicaments to ambulatory patients have been suggested in the past. Many of the devices seek either to improve or to replace the traditional gravity flow and hypodermic syringe methods which have been the standard for delivery of liquid medicaments for many years.

The prior art gravity flow methods typically involve the use of intravenous administration sets and the familiar flexible solution bag suspended above the patient. Such gravametric methods are cumbersome, imprecise and require bed confinement of the patient. Periodic monitoring of the apparatus by the nurse or doctor is required to detect malfunctions of the infusion apparatus. Accordingly, the prior art devices are not well suited for use in those instances where the patient must be transported to a remote facility for treatment.

As will be fully appreciated from the discussion that follows, the devices of the present invention are particularly useful in ambulatory situations. The ability to quickly and efficaciously treat wounded soldiers, especially in unpredictable or remote care settings, can significantly improve chances for patient survival and recovery. Accurate intravenous (IV) drug and fluid delivery technologies for controlling pain, preventing infection, and providing a means for IV access for rapid infusions during patient transport are needed to treat almost all serious injuries.

It is imperative that battlefield medics begin administering life saving medications as soon as possible after a casualty occurs. The continuous maintenance of these treatments is vital until higher echelon medical facilities can be reached. A compact, portable and ready to use infusion device that could be easily brought into the battlefield would allow medics to begin drug and resuscitation agent infusions immediately. Additionally, it would free them to attend to other seriously wounded patients who may require more hands-on care in the trauma environment following triage. In most serious trauma situations on the battlefield, IV drug delivery is required to treat fluid resuscitation, as well as both pain and infection.

Drug infusion devices currently available can impede administration of IV infusions in remote care settings.

Expensive electronic infusion pumps are not a practical field solution because of their weight and cumbersome size. Moreover, today's procedures for starting IV infusions on the battlefield are often dangerous because the attending medic must complete several time consuming steps. The labor intensive nature of current gravity solution bag modalities can prevent medics from attending to other patients also suffering from life threatening injuries. In some cases, patients themselves have been forced to hold flexible infusion bags elevated, in order to receive the medication by gravity drip.

With regard to the prior art, one of the most versatile and unique fluid delivery apparatus developed in recent years is that developed by one of the present inventors and described in U.S. Pat. No. 5,205,820. The components of this novel fluid delivery apparatus generally include: a base assembly, an elastomeric membrane serving as a stored energy means, fluid flow channels for filling and delivery, flow control means, a cover, and an ullage which comprises a part of the base assembly.

Another prior art patent issued to one of the present applicants, namely U.S. Pat. No. 5,743,879, discloses an injectable medicament dispenser for use in controllably dispensing fluid medicaments such as insulin, anti-infectives, analgesics, oncolylotics, cardiac drugs biopharmaceuticals, and the like from a pre-filled container at a uniform rate. The dispenser, which is quite dissimilar in construction and operation from that of the present invention, includes a stored energy source in the form of a compressively deformable, polymeric elastomeric member that provides the force necessary to controllably discharge the medicament from a pre-filled container, which is housed within the body of the device. After having been deformed, the polymeric, elastomeric member will return to its starting configuration in a highly predictable manner.

BRIEF SUMMARY OF THE INVENTION

By way of brief summary, one form of the dispensing device of the present invention for dispensing medicaments to a patient comprises a supporting structure; a carriage assembly interconnected with the supporting structure for movement between a first position and a second position; a pre-filled collapsible container carried by the carriage assembly, the collapsible container having accessing means for accessing the reservoir comprising a frangible member in the form of a pierceable member or a shearable member. The device also includes a guide means connected to the supporting structure for guiding travel of the carriage assembly between the first position and said second positions; a stored energy source operably associated with the carriage assembly for moving the carriage assembly between the first and second positions; and an administration set, including an administration line interconnected with the outlet port of the collapsible reservoir.

With the forgoing in mind, it is an object of the present invention to provide a compact fluid dispenser for use in controllably dispensing fluid medicaments to ambulatory patients, such as, antibiotics, blood clotting agents, analgesics, KVO, artificial blood substitutes, resuscitation fluids, nutritional solutions, biologics, and like agents from pre-filled containers at a uniform rate.

Another object of the invention is to provide a small, compact pre-filled fluid dispenser that is aseptically filled and sealed at the time of manufacture.

Another object of the invention is to provide a fluid dispenser of simple construction that can be used in the field with a minimum amount of training.

Another object of the invention is to allow infusion therapy to be initiated quickly and easily on the battlefield so that the attending medic or medical professional can more efficiently deal with triage situations in austere environments.

Another object of the invention is to provide a dispenser in which a stored energy source is provided in the form of a compressible, expandable or retractable member of novel construction that provides the force necessary to continuously and uniformly expel fluid from the device reservoir.

Another object of the invention is to provide a dispenser of the class described which includes a fluid flow control assembly that precisely controls the flow of the medicament solution to the patient.

Another object of the invention is to provide a dispenser that includes precise variable flow rate selection.

Another object of the invention is to provide a fluid dispenser of simple construction, which embodies a collapsible, pre-filled, sealed drug container that contains the beneficial agents to be delivered to the patient. Uniquely, the container is formed as a unitary structure that includes a collapsible side wall and pierceable closure wall that isolates the beneficial agents contained within the container reservoir from external contaminants.

Another object of the invention is to provide a fluid dispenser as described in the preceding paragraph, which embodies a collapsible, pre-filled drug container that includes an integrally formed, sealed reservoir that contains the beneficial agents to be delivered to the patient and is provided with access assemblies of various configurations that enable ready access to the sealed reservoir be penetrating assemblies various configurations.

Another object of the invention is to provide a fluid dispenser of the class described which is compact, lightweight, is easy for ambulatory patients to use, is fully disposable, transportable, and is extremely reliable in operation.

Another object of the invention is to provide a fluid dispenser as described in the preceding paragraphs that is easy and inexpensive to manufacture in large quantities.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

FIG. **1** is a generally perspective top view of one form of the fluid dispensing device of the present invention for dispensing medicaments to a patient.

FIG. **2** is a generally perspective bottom view of the fluid dispensing device shown in FIG. **1**.

FIG. **3** is a generally perspective view of the fluid dispensing device shown in FIG. **1** as it appears with the top cover of the device removed.

FIG. **4** is an enlarged, foreshortened, longitudinal, cross-sectional view of the pre-filled fluid dispensing device illustrated in FIG. **1**.

FIG. **5** is a longitudinal, cross-sectional view similar to FIG. **4**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **6** is a cross-sectional view taken along lines **6-6** of FIG. **5**.

FIG. **7** is a cross-sectional view taken along lines **7-7** of FIG. **5**.

FIG. **8** is a generally perspective, exploded view of the fluid delivery device illustrated in FIG. **3**.

FIG. **9** is a top plan view of the fluid reservoir assembly of the invention.

FIG. **10** is a cross-sectional view taken along lines **10-10** of FIG. **9**.

FIG. **11** is an enlarged cross-sectional view of the area designated in FIG. **10** by "11".

FIG. **12** is a side elevational view of one form of the control shaft of the flow control means of the invention.

FIG. **13** is a view taken along lines **13-13** of FIG. **12**.

FIG. **14** is a view taken along lines **14-14** of FIG. **12**.

FIG. **15** is an enlarged cross-sectional view taken along lines **15-15** of FIG. **12**.

FIG. **16** is an enlarged front view of one form of the spring knife of the invention that is carried within cavities formed in the control shaft shown in FIG. **12**.

FIG. **17** is a view taken along lines **17-17** of FIG. **16**.

FIG. **18** is an enlarged cross-sectional view of a portion of the support structure and of the control shaft of the device illustrating the appearance of the components in their starting position.

FIG. **19** is a cross-sectional view similar to FIG. **18** but showing the appearance of the components after the initial rotation of the control shaft from a first position to a second position.

FIG. **20** is a cross-sectional view similar to FIG. **19** but showing the appearance of the components after further rotation of the control shaft from the second position to a third position.

FIG. **21** is a top plan view of the operating handle of the device that is used for rotating the control shaft.

FIG. **22** is a view taken along lines **22-22** of FIG. **21**.

FIG. **23** is a top plan view of one form of the selector member of the device for selecting the rate of fluid flow toward the patient.

FIG. **24** is a cross-sectional view taken along lines **24-24** of FIG. **23**.

FIG. **24**A is a view taken along lines **24**A-**24**A of FIG. **24**.

FIG. **24**B is a cross-sectional view taken along lines **24**B-**24**B of FIG. **24**.

FIG. **25** is a view taken along lines **25-25** of FIG. **24**.

FIG. **26** is a top plan view of the retainer member of the device which functions to retain the selector member in position.

FIG. **27** is a cross-sectional view taken along lines **27-27** of FIG. **26**.

FIG. **27**A is a cross-sectional view taken along lines **27**A-**27**A of FIG. **26**.

FIG. **28** is a top plan view of the selector member housing of the device.

FIG. **29** is a cross-sectional view taken along lines **29-29** of FIG. **28**.

FIG. **30** is a view taken along lines **30-30** of FIG. **29**.

FIG. **31** is a top plan view of the rate control housing of the device which houses the rate control assembly.

FIG. **32** is a cross-sectional view taken along lines **32-32** of FIG. **31**.

FIG. **33** is a view taken along lines **33-33** of FIG. **32**.

FIG. **34** is a top plan view of a portion of the supporting structure of the device shown in FIG. **1**.

FIG. **35** is a cross-sectional view taken along lines **35-35** of FIG. **34**.

FIG. **35**A is a view taken along lines **35**A-**35**A of FIG. **35**.

FIG. **36** is a top plan view of the rate control assembly of the present form of the invention.

FIG. **37** is a cross-sectional view taken along lines **37-37** of FIG. **36**.

FIG. **38** is a view taken along lines **38-38** of FIG. **37**.

FIG. **39** is a top plan view of the upper cover of the rate control assembly shown in FIG. **36**.

FIG. **40** has a cross-sectional view taken along lines **40-40** of FIG. **39**.

FIG. **41** is a view taken along lines **41-41** of FIG. **40**.

FIG. **42** is a top plan view of one form of the rate control plate of the rate control assembly of the invention.

FIG. **43** is a cross-sectional view taken along lines **43-43** of FIG. **42**.

FIG. **44** is a view taken along lines **44-44** of FIG. **43**.

FIG. **45** is a top plan view of the bottom cover of the rate control assembly of the invention.

FIG. **46** is a cross-sectional view taken along lines **46-46** of FIG. **45**.

FIG. **47** is a view taken along lines **47-47** of FIG. **46**.

FIG. **47**A is an exploded, generally perspective, diagrammatic view of rate control portion of the device of the invention illustrating the manner of fluid flow from the device reservoir toward the administration set of the invention.

FIG. **48** is a top plan view of the carriage component of the device of the invention which supports the reservoir assembly.

FIG. **49** is a cross-sectional view taken along lines **49-49** of FIG. **48**.

FIG. **50** is a top plan view of a portion of the structural support of the device of the invention which supports the carriage component shown in FIGS. **48** and **49**.

FIG. **51** is a foreshortened, cross-sectional view taken along lines **51-51** of FIG. **50**.

FIG. **52** is a view taken along lines **52-52** of FIG. **51**.

FIG. **53** is cross-sectional view of the locking means of the invention for releasably locking the carriage to the portion of the structural support shown in FIGS. **50** and **51**.

FIG. **54** is a view taken along lines **54-54** of FIG. **53**.

FIG. **55** is a view taken along lines **55-55** of FIG. **53**.

FIG. **56** is an enlarged, foreshortened, longitudinal, cross-sectional view of an alternate form of the fluid dispensing device of the invention.

FIG. **57** is a longitudinal, cross-sectional view similar to FIG. **56**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **58** is a cross-sectional view of the collapsible container of this alternate embodiment of the invention.

FIG. **59** is a top plan view of the collapsible container.

FIG. **60** is a cross-sectional view taken along lines **60-60** of FIG. **59**.

FIG. **61** is a cross-sectional view of the area designated as "**61**" in FIG. **60**.

FIG. **62** is a generally perspective view of this alternate embodiment of the invention as it appears with the top cover of the device removed.

FIG. **63** is a longitudinal cross-sectional view of still another form of the fluid dispensing device of the invention.

FIG. **64** is a longitudinal cross-sectional view similar to FIG. **63** but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **65** is a view taken along lines **65-65** of FIG. **64**.

FIG. **66** is a view taken along lines **66-66** of FIG. **64**.

FIG. **67** is a cross-sectional view of the collapsible container of this latest form of the invention.

FIG. **68** is a top plan view of the collapsible container shown in FIG. **67**.

FIG. **69** is a cross-sectional view taken along lines **69-69** of FIG. **68**.

FIG. **70** is a top plan view of the pierceable septum of the collapsible container shown in FIG. **67**.

FIG. **71** is a cross-sectional view taken along lines **71-71** of FIG. **70**.

FIG. **72** is a bottom plan view of the septum penetrating assembly of this latest form of the invention.

FIG. **73** is a cross-sectional view taken along lines **73-73** of FIG. **72**.

FIG. **74** is a view taken along lines **74-74** of FIG. **73**.

FIG. **75** is a generally perspective view of this latest embodiment of the invention as it appears with a top cover of the device removed.

FIG. **76** is an enlarged, foreshortened, longitudinal, cross-sectional view of the fluid dispensing device of this latest embodiment the invention illustrating the removal of the tear off strip of the device.

FIG. **77** is a foreshortened, longitudinal, cross-sectional view of an alternate form of the fluid dispensing device of the invention.

FIG. **78** is a foreshortened longitudinal, cross-sectional view similar to FIG. **77**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **79** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **80** is a cross-sectional view taken along lines **80-80** of FIG. **79**.

FIG. **81** is an exploded, cross-sectional view of the reservoir access assembly of this latest form of the invention.

FIG. **82** is a fragmentary, cross-sectional view of the collapsible container as it appears in the collapsed configuration.

FIG. **83** is a foreshortened, longitudinal, cross-sectional view of yet another alternate form of the fluid dispensing device of the invention.

FIG. **84** is a foreshortened longitudinal, cross-sectional view similar to FIG. **83**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **85** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **86** is a foreshortened, cross-sectional view taken along lines **86-86** of FIG. **85**.

FIG. **87** is an exploded, cross-sectional view of the reservoir access assembly of this latest form of the invention.

FIG. **88** is a foreshortened, longitudinal, cross-sectional view of an alternate form of the fluid dispensing device of the invention.

FIG. **89** is a foreshortened longitudinal, cross-sectional view similar to FIG. **88**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **89**A is a fragmentary, cross-sectional view of the collapsible container as it appears in the collapsed configuration.

FIG. **90** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **91** is a cross-sectional view taken along lines **91-91** of FIG. **90**.

FIG. **92** is a foreshortened, longitudinal, cross-sectional view of still another alternate form of the fluid dispensing device of the invention.

FIG. **93** is a foreshortened longitudinal, cross-sectional view similar to FIG. **92**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **94** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **95** is a foreshortened, cross-sectional view taken along lines **95-95** of FIG. **94**.

FIG. **96** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **97** is a foreshortened, longitudinal, cross-sectional view of another alternate form of the fluid dispensing device of the invention.

FIG. **98** is a foreshortened longitudinal, cross-sectional view similar to FIG. **97**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **99** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **100** is a cross-sectional view taken along lines **100-100** of FIG. **99**.

FIG. **101** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **102** is a foreshortened, longitudinal, cross-sectional view of yet another alternate form of the fluid dispensing device of the invention.

FIG. **103** is a foreshortened longitudinal, cross-sectional view similar to FIG. **102**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **104** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **105** is a foreshortened, cross-sectional view taken along lines **105-105** of FIG. **104**.

FIG. **106** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **107** is a foreshortened, longitudinal, cross-sectional view of still another alternate form of the fluid dispensing device of the invention.

FIG. **108** is a foreshortened longitudinal, cross-sectional view similar to FIG. **107**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **109** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **110** is a cross-sectional view taken along lines **110-110** of FIG. **109**.

FIG. **111** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **112** is a foreshortened, longitudinal, cross-sectional view of yet another alternate form of the fluid dispensing device of the invention.

FIG. **113** is a foreshortened longitudinal, cross-sectional view similar to FIG. **112**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **114** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **115** is a foreshortened, cross-sectional view taken along lines **115-115** of FIG. **114**.

FIG. **116** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **117** is a foreshortened, longitudinal, cross-sectional view of still another alternate form of the fluid dispensing device of the invention.

FIG. **118** is a foreshortened longitudinal, cross-sectional view similar to FIG. **117**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **119** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **120** is a cross-sectional view taken along lines **120-120** of FIG. **119**.

FIG. **121** is a cross-sectional, exploded view of the reservoir access assembly of this latest form of the invention.

FIG. **122** is a fragmentary, cross-sectional view of the collapsible container as it appears in the collapsed configuration.

FIG. **123** is a foreshortened, longitudinal, cross-sectional view of yet another alternate form of the fluid dispensing device of the invention.

FIG. **124** is a foreshortened longitudinal, cross-sectional view similar to FIG. **123**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **125** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **126** is a foreshortened, cross-sectional view taken along lines **126-126** of FIG. **125**.

FIG. **127** is a cross-sectional view of the Luer-like reservoir access assembly of this latest form of the invention.

FIG. **128** is a foreshortened, longitudinal, cross-sectional view of still another alternate form of the fluid dispensing device of the invention.

FIG. **129** is a foreshortened longitudinal, cross-sectional view similar to FIG. **128**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

FIG. **130** is a top plan view of the collapsible container of this alternate embodiment of the invention.

FIG. **131** is a cross-sectional view taken along lines **131-131** of FIG. **130**.

FIG. **132** is a fragmentary, cross-sectional view of the collapsible container as it appears in the collapsed configuration.

FIG. **133** is a foreshortened, longitudinal, cross-sectional view of still another alternate form of the fluid dispensing device of the invention.

FIG. **134** is a foreshortened longitudinal, cross-sectional view similar to FIG. **133**, but showing the various components of the device as they appear following delivery to the patient of the fluid contained within the device reservoir.

DETAILED DESCRIPTION OF THE INVENTION

Definitions

As used herein, the following terms have the following meanings:

Unitary Container

A closed container formed from a single component.

Continuous/Uninterrupted Wall.

A wall having no break in uniformity or continuity.

Biologic

A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of the human or animal body.

Hermetically Sealed Container

A container that is designed and intended to be secure against the entry of microorganisms and to maintain the safety and quality of its contents after pressurizing.

Drug

As defined by the Food, Drug and Cosmetic Act, drugs are "articles (other than food) intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or to affect the structure or any function."

Drug Product

A finished dosage form (e.g. tablet, capsule, or solution) that contains the active drug ingredient usually combined with inactive ingredients.

Artificial Blood Substitutes

Blood Substitutes are used to fill fluid volume and/or carry oxygen and other gases in the cardiovascular system. These include volume expanders for inert products, and oxygen therapeutics for oxygen-carrying products.

Resuscitation Fluids

Infusion of hyperosmotic-hyperoncotic solutions such as hypertonic saline dextran (HSD) as used for resuscitation of traumatic shock and perioperative volume support or as an adjunct to other conventional isotonic crystalloid solutions. Where hypotension is caused by myocardial depression, pathological vasodilatation and extravascation of circulating volume due to widespread capillary leak, a resuscitative effort is attempted to correct the absolute and relative hypovolemia by refilling the vascular tree. Here resuscitation with a small volume of hypertonic-hyperoncotic solution allows systemic and splanchnic hemodynamic and oxygen transport recovery, without an increase in pulmonary artery pressure. Alternate types of normotonic, hyperoncotic, hypertonic, and hypertonic-hyperoncotic solutions can be used for systemic hemodynamic recovery.

KVO

KVO—keeping-the-vein-open in an IV set up; is a phrase that refers to the flow rate of a maintenance IV line established as a prophylactic access.

Nutritionals

Dietary supplemental enteral nutrition support feeding solutions used for nasoenteric application typically used in nasogastric, nasoduodenal, nasojejunal, or intravenous routes of administration.

Beneficial Agent

The term beneficial agent can include any substance or compound that is biologically active and includes any physiologically or pharmacologically active substance that produces a localized or systemic effect in humans or animals and that can be delivered by the present invention to produce a beneficial and useful result.

Diluent

A liquid that which dilutes, as in an inert solution used to dilute a medicament. An inert liquid carrier of a beneficial agent.

Device

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis, cure, treatment or prevention of disease. A device does not achieve its intended purpose through chemical action in the body and is not dependent upon being metabolized to achieve its purpose.

Apparatus

An appliance or device for a particular purpose: An integrated group of materials or devices used for a particular purpose. The totality of means by which a designated function is performed or a specific task executed; a group of body parts that work together to perform a given function.

Reservoir

A receptacle or chamber for storing a fluid. A part of a machine, device, where liquid is stored.

Liquid Container

A receptacle for holding a liquid. A fluid dispenser that is carried or transported.

Collapsible

To cause to fold, break down, or fall down or inward or as in bent-over or doubled-up so that one part lies on another.

Collapsible Container

A dispensing device in which one or more walls of the container are made of a material, which will deform (collapse) when pressure is applied thereto; or a dispensing device having a collapsible or telescoping wall structure.

Aseptic Processing

The term 'aseptic processing' as it is applied in the pharmaceutical industry refers to the assembly of sterilized components and product in a specialized clean environment.

Sterile Product

A sterile product is one that is free from all living organisms, whether in a vegetative or spore state.

Blow-Fill-Seal Process

The concept of aseptic blow-fill-seal (BFS) is that a container is formed, filled, and sealed as a unitary container in a continuous manner without human intervention in a sterile enclosed area inside a machine. The process is multi-stepped, pharmaceutical grade resin is extruded into a tube, which is then formed into a container. A mandrel is inserted into the newly formed container and filled. The container is then sealed, all inside a sterile shrouded chamber. The product is then discharged to a non-sterile area for packaging and distribution.

Integrally Formed

An article of one-piece construction, or several parts that are rigidly secured together, smoothly continuous in form and that any such components making up the part have been then rendered inseparable.

Septum

A word borrowed from the Latin "saeptum" meaning a dividing wall or enclosure; thus, a thin partition or membrane that divides two spaces.

Slit Septum

A septum that is partially slit to aid in cannula penetration.

Penetrating

Tending to penetrate; having the power of entering or piercing.

Cutting

Capable of or designed for incising, shearing, or severing as to cut off from a main body.

Frangible

An article, item or object that is capable of being ruptured or broken, but does not necessarily imply any inherent materials weakness. A material object under load, that demonstrates a mechanical strain rate deformation behavior leading to disintegration.

Luer-Like Connector

A connector used to connect medical devices. Classically, the Luer consists of a tapered barrel and a conical male part that fits into it with or without a seal.

Surface Treatment

The processes of surface treatments, more formally surface engineering, to tailor the surfaces of engineering materials to change, alter or modify the physical surface characteristics and improve the function of the materials properties for its intended purpose.

Spring

A mechanical element that can be deformed by a mechanical force such that the deformation is directly proportional to the force or torque applied to it. An elastic machine component able to deflect under load in a prescribed manner and to

recover its initial shape when unloaded. The combination of force and displacement in a deflected spring is energy, which may be stored when moving loads are being arrested.

Constant Force Spring

Constant force springs are a special variety of extension spring. They are tightly coiled wound bands of pre-hardened spring steel or stainless steel strip with built-in curvature so that each turn of the strip wraps tightly on its inner neighbor. When the strip is extended (deflected), the inherent stress resists the loading force, the same as a common extension spring but at a nearly constant (zero) rate. The constant-force spring is well suited to long extensions with no load build-up. In use, the spring is usually mounted with the ID tightly wrapped on a drum and the free end attached to the loading force. Considerable flexibility is possible with constant-force springs because the load capacity can be multiplied by using two or more strips in tandem, or back-to-back. Constant force springs are available in a wide variety of sizes.

Apparatus of the Invention

Referring to the drawings and particularly to FIGS. **1** through **8**, one form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **50**. The dispensing device here includes a supporting structure **52**, which includes a connector assembly **54** and a generally cylindrically shaped outer housing **56** that is interconnected with the connector assembly in the manner best seen in FIG. **4** of the drawings. Supporting structure **52** can be constructed from metal, plastic or any suitable material. Outer housing **56** includes a generally cylindrically shaped wall portion **56***a* and a threaded base portion **56***b*, the purpose of which will presently be described.

Disposed within wall portion **56***a* is a carriage assembly **58**, which is movable between a first position shown in FIG. **4** and a second position, shown in FIG. **5**. As best seen by referring to FIGS. **4** and **7**, carriage assembly **58** comprises a carriage **60** having a carriage base **60***a* that is provided with a plurality of circumferentially spaced openings **62** and a generally cylindrically shaped sidewall **60***b* which terminates in a radially outwardly extending flange **60***c*. Carriage assembly **58** is releasably locked in its first position by a novel locking means the character of which will presently be described.

Carried by carriage assembly **58** is a reservoir defining assembly **64** that defines a fluid reservoir **65**. As indicated in FIG. **4**, reservoir **65** has a combination inlet/outlet **66** that is formed in a shearable reservoir nipple **68***b* that comprises a part of the reservoir assembly **64**. Nipple **68** is connected to an accordion-like member **70** that also comprises a part of the reservoir assembly **64** (FIGS. **4** and **10**). Locking teeth **69** which circumscribe nipple **68** hold the assembly **64** in place. Reservoir assembly **64** can be constructed from low and high density polyethylene and polypropylene and like polymers.

In the preferred form of the invention, nipple **68** is sealably interconnected with member **70** in accordance with an aseptic blow-fill-seal technique. This technique involves the continuous extrusion through an extruder head of a length of parison in the form of a hollow tube between and through two co-acting first or main mold halves. The method includes the step of cutting off the parison below the extruder head and above the main mold halves to create an opening which allows a blowing and filling nozzle assembly to be moved downwardly into the opening in the parison for molding and thereafter filling a molded container.

When the container is filled with the desired amount of liquid, the blowing and filling nozzle assembly is retracted from the opening in the parison. A separate pair of co-acting second or upper sealing mold halves are then moved together around the exposed length of parison to form and seal the container upper portion. The finished container, completely formed, filled, and sealed as a unitary structure is then conveyed out of the apparatus. Reference should also be made to U.S. Pat. No. 6,145,285 issued to Anderson, which discloses an improved method and apparatus for molding containers using aseptic blow-fill-seal techniques. Further information concerning aseptic blow-fill-seal techniques is available from Weiler Engineering of Elgin, Ill.

An important feature of the present invention resides in the provision of novel guide means for guiding travel of carriage assembly **58** between the first position shown in FIG. **4** and the second position shown in FIG. **5**. In the present form of the invention this important guide means comprises a plurality of circumferentially spaced guide members **74** which are connected to and extend outwardly from connector **54***b* of connector assembly **54** (FIGS. **4**, **6** and **7**). As indicated in the drawings, guide members **74** are slidably received within openings **62** provided in carriage base **60***a* so that as the carriage assembly travels from its first position toward its second position, guide members **74** precisely guide its travel. Also forming a part of the guide means of the apparatus of the present invention are a plurality of circumferentially spaced guide ribs **76** that are formed on the inner wall of outer housing **56** (FIGS. **6** and **7**).

To controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled compression spring **80**. As illustrated in FIGS. **4** and **5**, one end **80***a* of the coil spring **80** is disposed in engagement with the threaded base portion **56***b* of outer housing **56** of the supporting structure and the other end **80***b* thereof is disposed in engagement with radially outwardly extending flange **60***c* of carriage **60**. With this construction, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **56***b* of the outer housing, spring **80** will move from its retracted position shown in FIG. **4** to its expanded position shown in FIG. **5**, and in so doing will controllably move the carriage assembly **58** from its starting position shown in FIG. **4** to its fully deployed, or extended position shown in FIG. **5**. As will be described more fully in the paragraphs which follow, as the carriage assembly moves toward its deployed position, the accordion sidewall **70***a* of the bellows member **70** will move into the collapsed configuration shown in FIG. **5** and in so doing will cause the medicinal fluid contained within the container to be controllably substantially expelled therefrom.

To further control the flow of medicinal fluid from reservoir **65** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. This novel fluid flow control means, which is carried by connector assembly **54** of the supporting structure **52**, here comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means.

Considering first the rate control means of the invention, which is illustrated in FIGS. **31** through **47**, this important means comprises a rate control housing **84**, which includes a generally annular-shaped cavity **84***a* (see FIGS. **5** and **32**) that closely receives a collar **86** formed on connector **54***a* of connector assembly **54** (see also FIG. **35**). As best seen in FIG. **32**, rate control housing **84** includes a rate control cavity **88** and an outwardly extending, shearable nipple **90**, the purpose of which will presently be described. Interconnected with a

rate control housing **84** is a selector member housing **92**, that includes a skirt **94** that circumscribes rate control housing **84** (FIGS. **4** and **29**). Selector member housing **92** also includes an outwardly extending flange **96** which defines a cylindrical space about which the administration line **82***a* of the administration set can be coiled in the manner best seen in FIG. **4**. Additionally, selector member housing **92** is provided with a plurality of circumferentially spaced cavities (FIGS. **29** and **30**), which are adapted to sealably receive circumferentially spaced-apart outlet ports **100** that are formed on rate control cover **102** of the rate control assembly **104** of the present invention (see FIGS. **36** and **37**). In order to ensure a positive seal, the outlet ports **100** are provided with elastomeric collars **101** which are sealably received around the circumferentially spaced-apart outlet ports **100**.

As illustrated in FIG. **4**, rate control assembly **104**, which forms a part of the rate control means of the invention, is closely received within rate control cavity **88** and is held in position there within by rate control housing **84**. In addition to rate control cover **102**, rate control assembly **104** includes a second, mating rate control cover **106** and a novel rate control plate **110** (FIG. **42**), that is disposed between covers **102** and **106**. As will presently be described, rate control plate **110** can be constructed from a variety of plastic materials and is provided with a plurality of fluid flow channels **112** of different lengths, widths, depths and geometry that are in fluid communication with outlet **66** of collapsible reservoir **65**.

As previously discussed, the rate control means of the invention includes selector means for selecting the rate of fluid flow between collapsible reservoir **65** and the administration set **82** of the invention. In addition to the previously identified selector member housing **92**, the selector means includes a selector member **116** that is held in position by a retainer member **159**, and is rotatably carried by the selector housing (FIG. **4**). A plurality of O-rings **117** which circumscribe the body portion of selector member **116**, provide a substantially leak-tight seal between the components. Selector member **116** carries a pierceable drug recovery septum **119**, which forms a part of the recapture means of the invention and includes an axially extending fluid passageway **116***a*, that provides fluid communication between septum **119** and the fluid reservoir via rate control assembly **104** and frangible nipple **90**. As will be discussed in the paragraphs which follow, selector member **116** is also provided with a plurality of circumferentially extending passageways that communicate with the rate control passageways formed in rate control plate **110** via fluid passageways formed in selector member housing **92** (see FIG. **47**A).

Considering next the previously identified operating means of the invention, which is illustrated in FIGS. **12** through **20**, this important operating means, which controls fluid flow between collapsible reservoir **64** and the rate control means, here comprises an operating shaft **122** that is rotatably mounted within a generally cylindrically shaped chamber **124** formed in connector **54** of supporting structure **52**. Operating shaft **122** can be rotated within chamber **124**, which is closed by a cap **124***a*, by an "L"-shaped operating handle **126** (FIG. **3**) between a first position shown in FIG. **18** blocking fluid flow from collapsible reservoir **64** toward administration set **82** and a second position shown in FIG. **20** permitting fluid flow from the reservoir toward the administration set.

Turning particularly to FIGS. **12** and **15**, operating shaft **122** can be seen to comprise a body portion **122***a* and a reduced diameter neck portion **122***b*. Circumferentially spaced-apart, generally arcuate-shaped cavities **130** and **132**, which are formed in body portion **122***a*, are strategically located to receive the end portions of nipples **68** and **90** when the operating shaft is in held in position within chamber **124** by retainer clips **125** in the manner shown in FIG. **4**. Also formed within operating shaft **122** is a transversely extending fluid passageway **134**, which, upon rotation of the operating shaft by handle **126**, can be moved into alignment with the fluid passageways **68***a* and **90***a* of nipples **68** and **90** respectively (see FIG. **20**).

Mounted within each of the cavities **130** and **132** is a spring knife **136** which, as indicated in FIGS. **16** and **17**, includes a cutting edge **136***a* formed proximate one extremity and a pair of mounting clips **137** provided proximate the opposite extremity. Tabs **137***a* of the mounting clips are received within slots **139** formed in body portion **122***a* so as to secure the spring knives within the arcuate cavities in the manner illustrated in FIG. **15**. With this construction, as the operating shaft **122** is rotated by handle **126** from the position shown in FIG. **18** into the position shown in FIG. **19** the spring knives will cleanly sever the sealed tip portions **68***b* and **90***b* of the frangible, shearable nipples **68** and **90** respectively. Continued rotation of operating member **122** will move sealed tip portions **68***b* and **90***b* into the cavities for rotation therewith (FIG. **19**) and will move transverse passageway **134** into alignment with passageways **68***a* and **90***a* in a manner shown in FIG. **20**. With the operating member in this position fluid can flow freely from reservoir **65** toward the rate control means of the invention via passageways **68***a* and **90***a* of nipples **68** and **90**.

From passageway **90***a* fluid will flow through a conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels **112***a*, **112***b*, **112***c*, **112***d*, **112***e* and **112***f* formed in the rate control plate, each of which may be of a different length, width, depth and geometry (see FIGS. **42** and **47**A). As each of the channels fills with the medicinal fluid to be dispensed to the patient, the fluid will flow into outlet passageways **100***a*, **100***b*, **100***c*, **100***d*, **100***e* and **100***f* respectively formed in rate control cover **102**. From these outlet passageways, the fluid flows into and fills circumferentially spaced-apart fluid passageways **144***a*, **144***b*, **144***c*, **144***d*, **144***e* and **144***f* formed in selector housing **92** (see FIG. **30**).

As best seen by referring to FIG. **24**, selector member **116** is provided with an inlet passageway **146** and an outlet passageway **148** that is interconnected with inlet passageway **146** by means of an axially extending stub passageway **150** which, in turn, is connected to a circumferentially extending passageway **151** formed in selector member **116** (FIG. **47**A). With this construction, by rotating the selector member **116**, inlet passageway **146** can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **92** thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector housing **92**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length that is formed in rate control plate **110**.

With the device in the configuration shown in FIGS. **1**, **2** and **4**, and with the fluid reservoir **65** filled with the medicament to be dispensed to the patient, the dispensing operation can be commenced by removing the top cover **153**, which is snapped over a cover connector **155** that protrudes from the structural member **54***a*. With the cover removed, the admin-

istration line **82***a* of the administration set **82** can be unwrapped from the selector member housing, about which it has been coiled (see FIGS. **3** and **4**). Removal of the top cover **153** also exposes the selector member **116** so that the fluid flow rate can be selected by actioning the interlock **116***r* and rotating the selector member to the desired flow rate indicated by the indicia **157** imprinted on the selector member component **116**. With the desired flow rate thusly set, the operating shaft **122** is next rotated through the use of the operating handle **126** from the starting position shown in FIG. **18** to the fully rotated position shown in FIG. **20**. In this way, communication is opened between the reservoir outlet **66** and passageway **90***a* of nipple **90** which, in turn, is in communication with the rate control assembly of the invention.

Following the controlled rotation of the operating shaft **122**, which is interconnected with structural member **54***a*, the carriage locking means of the invention can be manipulated in a manner to release the carriage **60** from base member **56***b* in order to permit the stored energy means, or spring **80**, to move the carriage from the starting position shown in FIG. **4** to the extended position shown in FIG. **5**. In this regard, as best seen in FIGS. **53** and **55**, the carriage locking means includes a locking member **164** having a shank portion **164***a* which extends through a keyhole-shaped opening **162** provided in the carriage base (see FIG. **48**) and a generally keyhole-shaped locking portion **164***b*. The carriage locking means also includes a finger-engaging, operating member **166** that includes a driving rib **166***a* that is received within a groove formed within shaft **164***a*. Operating member **166** functions to rotate locking member **164** from a transverse locking position to a release position in alignment with keyhole opening **162** formed in carriage base **60***d*. As indicated in FIGS. **51** and **52** base **56***b* of the supporting structure is provided with circumferentially spaced-apart indexing buttons **168** which are received within a button receiving cavity **166***b* formed in finger-engaging member **166** as the operating member is rotated from a locked position to a release position (FIG. **53**). As shown in FIG. **52**, to assist the caregiver in performing the carriage release step, base **56***b* is provided with indicia **169** indicating the locking and release position of the operating member **166**.

Following the release of the carriage assembly, the stored energy means, or coiled spring **80**, will move the carriage from a position shown in FIG. **4** into the position shown in FIG. **5** and in so doing will urge the fluid contained within reservoir **65** to flow toward reservoir outlet **66**, into passageway **134** formed in control member **122** and into passageway **90***a* of nipple **90**. From passageway **90***a*, fluid will flow into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels **112***a*, **112***b*, **112***c*, **112***d*, **112***e* and **112***f* formed in the rate control plate. As each of the channels fills with the medicinal fluid to be dispensed to the patient, the fluid will flow into outlet passageways **100***a*, **100***b*, **100***c*, **100***d*, **100***e* and **100***f* respectively formed in rate control cover **102**. From these outlet passageways, the fluid will flow into and fill the circumferentially spaced-apart fluid passageways **144***a*, **144***b*, **144***c*, **144***d*, **144***e* and **144***f* formed in selector housing **92** (see FIG. **30**).

As previously discussed, by rotating the selector member **116**, inlet passageway **146** of selector member **116** can be selectively brought into index with one of the radial extensions **147** of the passageways formed in selector member housing **92** thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways **112** (see FIGS. **24** and **29**) formed in rate control plate **110**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length that is formed in rate control plate **110** (see FIG. **47**A).

In the present form of the invention, administration set **82**, which comprises a part of the dispensing means of the invention for delivering medicinal fluids to the patient, includes, in addition to administration line **82***a*, a conventional "Y"-site injection septum or port **172**, a conventional gas vent and particulate filter **174** and a line clamp **176**. Provided at the distal end of the administration line is a luer connector **178** of conventional construction (FIG. **3**) which enables the device to be interconnected with the patient in a conventional manner.

In those special instances where reservoir **65** has not been filled with the medicament at the time of manufacture, the reservoir can be expeditiously filled in the field by a relatively simple procedure. More particularly, after rotating the control shaft in the manner previously described and to sever the sealed tip portions of the nipples **70** and **90**, the medicament to be delivered to the patient can be transferred from a conventional syringe or the like to reservoir **65** via pierceable drug recovery septum **119**, fluid passageway **116***a*, rate control assembly **104** and passageways **90***a* and **70***a* of nipples **90** and **70** (see FIGS. **5** and **47**A).

Using a conventional syringe, or like device, pierceable septum **119** can also be used to recover any medicament that may remain in reservoir **65** following the fluid delivery step.

Turning now to FIGS. **56** through **62**, an alternate form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **200**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **1** through **55** and like numerals are used in FIGS. **56** through **62** to identify like components. As before, the dispensing device here includes a supporting structure **52** which includes a connector assembly **54** and a generally cylindrically shaped outer housing **56** that is interconnected with the connector assembly in the manner best seen in FIG. **56** of the drawings.

Disposed within wall portion **56***a* is a carriage assembly **58** which is movable between a first position shown in FIG. **56** and a second position shown in FIG. **57**. Carriage assembly **58** is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical to the locking means previously described herein.

The primary difference between this latest form of dispensing device of the invention and that previously described resides in the provision of a reservoir defining assembly **202** of a totally different construction. Reservoir defining assembly **202** here comprises a collapsible container assembly **204** which is carried by carriage assembly **58** in the manner illustrated in FIG. **56**.

As best seen by referring to FIGS. **58** through **61**, collapsible container assembly **204** includes a collapsible, telescoping sidewall **204***a*, an interconnected bottom wall **204***b* and an interconnected top wall **204***c* to which a sealed reservoir nipple **206** is integrally formed and sealably interconnected. Collapsible container assembly **204** defines a fluid reservoir **207** having an inlet/outlet that is generally identified by the numeral **208**.

In the preferred form of this alternate embodiment of the invention, shearable nipple **206** is integrally formed and sealably interconnected with member top wall **204***c* in accordance with an aseptic blow-fill-seal technique of the general character previously described to form a unitary structure.

As in the earlier described embodiment of the invention, an important feature of this latest form of the invention resides in the provision of novel guide means for guiding travel of carnage assembly **58** between the first position shown in FIG. **56** and the second position shown in FIG. **57**. This important guide means is of identical construction and operation to that previously described herein.

To controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled spring **80** which is also identical in construction and operation to that previously described.

As in the earlier described embodiment of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **56***b* of the outer housing, spring **80** will move from its compressed position shown in FIG. **56** to its expanded position shown in FIG. **57** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **56** to its fully deployed, or extended, position shown in FIG. **57**. As the carriage assembly moves toward its deployed position, the collapsible sidewall **204***a* of the collapsible container **204** will move into the collapsed configuration shown in FIGS. **57** and **60**. As the collapsible container collapses, the sidewalls will telescope and the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **207** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. This novel fluid flow control means, which is identical in construction and operation to that previously described, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. These important components are fully described in the preceding paragraphs.

As in the earlier described embodiment of the invention, the important operating means, which controls fluid flow between collapsible reservoir **207** and the rate control means, here comprises an operating shaft **122** that is rotatably mounted within a generally cylindrically shaped chamber **124** formed in connector **54***a* of supporting structure **52**. As before, operating shaft **122** can be rotated within chamber **124** by an "L"-shaped operating handle **126** between a first position blocking fluid flow from collapsible reservoir **207** toward administration set **82** and a second position permitting fluid flow from the reservoir toward the administration set.

As illustrated in FIG. **56**, operating shaft **122** includes a body portion **122***a* and a reduced diameter neck portion **122***b*. Circumferentially spaced-apart generally arcuate-shaped cavities **130** and **132**, which are formed in body portion **122***a*, are strategically located to receive the end portions of nipples **206** and **90** when the operating shaft is in held in position within chamber **124** by retainer clips **125** in the manner shown in FIG. **56**. Also formed within operating shaft **122** is a transversely extending fluid passageway **134** which, upon rotation of the operating shaft by handle **126**, can be moved into alignment with the fluid passageways **206***a* and **90***a* of nipples **206** and **90** respectively.

Mounted within each of the cavities **130** and **132** is a spring knife **136**, which includes a cutting edge formed proximate one extremity and a pair of mounting clips provided proximate the opposite extremity. As the operating shaft **122** is rotated by the operating handle **126** from it first position into its second position the spring knives will cleanly sever or shear the sealed tip portions **206***b* and **90***b* of nipples **206** and **90** respectively. Continued rotation of operating member will move sealed tip portions **206***b* and **90***b* into the cavities for rotation therewith and will move transverse passageway **134** into alignment with passageways **206***a* and **90***a*. With the operating member in this position fluid can flow freely from reservoir **207** toward the rate control means of the invention via passageways **206***a* and **90***a* of nipples **206** and **90**.

From passageway **206***a*, fluid will flow through a conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **92** via rate control cover **102**. In operating the device in the manner previously described herein, by rotating the selector member **116**, inlet passageway **146** can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **92**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member housing **92**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via the annular grove and passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length, width, depth and geometry that is formed in rate control plate **110**.

As before, by using a conventional syringe, or like device, pierceable elastomeric septum **119** can be used to recover any medicament that may remain in reservoir **207** following the fluid delivery step.

Referring next to FIGS. **63** through **76**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **212**. This alternate form of dispensing device is similar in some respects to that shown in FIGS. **56** through **62** and like numerals are used in FIGS. **63** through **75** to identify like components. Because the flow control means of this latest form of the invention is of different construction and operates in a different way, the dispensing device **212** includes a supporting structure **214**, which, is of necessity, somewhat different in construction. More particularly, the supporting structure **214** here comprises a connector assembly **216** and a generally cylindrically shaped outer housing **218** that is interconnected with the connector assembly in the manner best seen in FIG. **63** of the drawings.

Disposed within outer housing **218** is the carriage assembly **58**, which is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **58** is a reservoir defining assembly **222**, which is of similar construction to reservoir assembly **204** and here includes a collapsible container assembly **224** made from a blow-fill process (as distinguished from a blow-fill-seal process) having a sidewall **224***a*, an interconnected bottom wall **224***b* and an interconnected top wall **224***c* to which the accessing means of the invention for accessing the reservoir of the container assembly. This novel accessing means is here shown as a sealed reservoir insert septum assembly **226** is sealably interconnected (see FIG. **67**). Collapsible container assembly **224** defines a fluid reservoir **227** that, in a manner presently to be described, is accessible via a

slit septum **230**, which has been insert-molded and comprises a part of reservoir sealing means or septum assembly **226**. As best seen in FIG. **67**, septum **230** is disposed within a generally cylindrically shaped holding ring **232**, which, in turn, is disposed within a housing **234** that is sealably interconnected with top wall **224***c*.

In the preferred form of this alternate embodiment of the invention, reservoir septum assembly **226** is sealably interconnected with top wall **224***c* in accordance with the previously described aseptic blow-fill-seal technique.

The primary difference between this latest form of dispensing device of the invention and those previously described herein resides in the provision of a totally different operating means for controlling fluid flow between the collapsible reservoir **224** and the rate control means.

As in the earlier described embodiments of the invention, novel guide means are provided for guiding travel of carriage assembly **58** between the first position shown in FIG. **63** and the second position shown in FIG. **64**. This important guide means is of identical construction and operation to that previously described herein.

Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled compression spring **80**, which is also of identical construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **218***a* of the outer housing **218**, spring **80** will move from its retracted position shown in FIG. **63** to its expanded position shown in FIG. **64** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **63** to its fully deployed or extended position shown in FIG. **64**. As the carriage assembly moves toward its deployed position, the collapsible sidewall **224***a* of the collapsible container **224** will move into the collapsed configuration shown in FIGS. **64** and **69**. As the walls of the collapsible container telescopically collapse, the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **227** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. As previously mentioned, the operating means of this latest form of the invention is a different construction and operation from the previously described operating means. However, the rate control means of this latest form of the invention is similar in construction to that previously described and the rate control assembly of the rate control means is identical in construction and operation to that previously described.

The important operating means of this latest embodiment of the invention, which controls fluid flow between reservoir **227** and the rate control means, here comprises a septum penetrating assembly generally designated by the numeral **238** (See FIGS. **72** through **74**). Assembly **238**, which is disposed within a skirt **240** formed on selector member housing **242**, includes internal threads **238***t* which threadably mate with external threads **216***t*. Assembly **238** also includes a septum penetrating member **244** which is received within a guide passageway **246** formed on support member **216** (FIG. **63**). Assembly **238** also includes a cavity **238***a*, which closely receives a portion of the rate control assembly **104**.

In this latest embodiment of the invention, selector member housing **242**, along with septum penetrating assembly **238** is movable within a guide sleeve **250** that extends outwardly from support member **216**, from the first position shown in FIG. **63** to the second position shown in FIG. **64**. In addition to guiding the travel of the septum penetrating assembly, guide sleeve **250** defines a cylindrical space **250***a* about which the administration line **82***a* of the administration set **82** can be coiled in the manner best seen in FIG. **63**.

Selector member housing **242** is retained in its first position by a tear strip **252** that is removably receivable between a circumferentially extending rib **242***a* formed on housing **242** and the upper extremity **250***b* of guide sleeve **250**. When the tear strip **252** is removed in the manner illustrated in FIG. **76**, a rotary force exerted on selector member housing **242** will cause the cooperative engagement of the mating threads **238***t* and **216***t* to move the housing along with the septum penetrating assembly into the second position shown in FIG. **64** and in so doing will cause the septum penetrating member **244** to pierce the septum in the manner shown in FIG. **64**. Piercing of the septum **230** opens a fluid communication path from reservoir **227** to the rate control assembly **104** via a central fluid passageway **244***a* formed in septum penetrating member **244**. From passageway **244***a*, fluid will flow through conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector member housing **242**, inlet passageway **144***a* can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **242**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member **242**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length, width, depth and geometry that is formed in rate control plate **110**.

As previously described, by using a conventional syringe, or like device, pierceable elastomeric drug recovery septum **119** can be used to recover any medicament that may remain in reservoir **227** following the fluid delivery step.

Turning next to FIGS. **77** through **82**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **262**. This alternate form of dispensing device is similar in some respects to that shown in FIGS. **63** through **76** and like numerals are used in FIGS. **77** through **82** to identify like components. As best seen in FIGS. **77** and **78**, the supporting structure **264** is similar in many respects to supporting structure **214** and here comprises a connector assembly **266** and a generally cylindrically shaped outer housing **268** that is interconnected with the connector assembly in the manner best seen in FIG. **77** of the drawings.

Disposed within outer housing **268** is the carriage assembly **58**, which is of identical construction and operation to that previously described and is releasably locked in its first posi-

tion by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **58** is a reservoir defining assembly **270**, which is of a somewhat different construction. This important reservoir defining assembly here includes an integrally formed collapsible container assembly **272** having a continuous wall including a sidewall **272***a*, an interconnected bottom wall **272***b*, an interconnected top wall **272***c* and an interconnected neck portion **272***d* which is sealed at the time of manufacture by a thin pierceable closure wall **274**. Neck portion **272***d*, which is preferably integrally formed with top wall **272***c*, forms a part of the novel reservoir access means of the invention. The collapsible container of container assembly **272** comprises a unitary structure that defines a fluid reservoir **277** that, in a manner presently to be described, is accessible via a penetrating member **280** that is adapted to pierce thin closure wall **274** as well as a pierceable membrane **282** which is positioned over closure wall **274** by means of a closure cap **284** which is affixed to the neck portion **272***d* of container assembly **272** (see FIGS. **80** and **81**). Penetrating member **280**, pierceable membrane **282** and closure cap **284** also form a part of the novel reservoir access means of the invention. Container assembly **272** can be interconnected with connector member **266** as a snapfit by a threaded construction or any other convenient mechanism.

In the preferred form of this latest alternate embodiment of the invention, closure wall **274** is sealably interconnected with neck portion **272***d* in accordance with the previously described aseptic blow-fill-seal technique.

The primary difference between this latest form of dispensing device of the invention and those previously described herein resides in the somewhat differently configured container assembly **272** and the somewhat differently configured penetrating member **280**. In constructing the container assembly **272**, the basic container is formed using the aseptic blow-fill-seal technique earlier described herein and the reservoir portion of the container is sealed by reservoir accessing means which comprises the thin closure wall **274**. The piercable membrane **282** is then positioned over the closure wall **274** and the cap **284** is positioned over the piercable membrane and secured to neck portion **272***d* by any suitable means such as adhesive bonding or sonic welding. Membrane **282**, cap **284** and neck portion **272***d* all comprise a part of the reservoir accessing means of this latest form of the invention. It is important to note that closure wall **274** effectively prevents the medicament contained within the fluid reservoir from coming in contact with the membrane **282** at any time prior to accessing the reservoir.

As in the earlier described embodiments of the invention, novel guide means are provided for guiding travel of carriage assembly **58** between the first position shown in FIG. **77** and the second position shown in FIG. **78**. This important guide means is of identical construction and operation to that previously described herein.

Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled spring **80**, which is also identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **268***a* of the outer housing **268**, spring **80** will move from its retracted position shown in FIG. **77** to its expanded position shown in FIG. **78** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **77** to its fully deployed or extended position shown in FIG. **78**. As the carriage assembly moves toward its deployed position, the collapsible sidewall **272***a* of the collapsible container **272** will move into the collapsed configuration shown in FIGS. **78** and **82**. As the collapsible container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **277** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. As previously mentioned, the operating means of this latest form of the invention is of a different construction and operation from the previously described operating means. However, the rate control means of this latest form of the invention is similar in construction to that previously described and the rate control assembly of the rate control means is identical in construction and operation to that previously described in connection with Figure drawings **36** through **74**A.

The important operating means of this latest embodiment of the invention, which controls fluid flow between collapsible reservoir **277** and the rate control means, here comprises a penetrating assembly generally designated by the numeral **288** (See FIGS. **77** and **78**). Assembly **288**, which is disposed within a skirt **240** formed on a selector member housing **242**, includes the previously identified penetrating member **280** which is sealably received within a guide passageway **290** formed on support member **266** (FIG. **77**). Assembly **288** also includes a cavity **288***a*, which closely receives a portion of the rate control assembly **104**.

In this latest embodiment of the invention, selector member housing **242**, along with septum penetrating assembly **288** is movable within a guide sleeve **250** that extends outwardly from support member **266**, from the first position shown in FIG. **77** to the second position shown in FIG. **78**. In addition to guiding the travel of the penetrating assembly, guide sleeve **250** defines a cylindrical space **252***a* about which the administration line **82***a* of the administration set **82** can be coiled in the manner best seen in FIG. **77**.

As in the earlier described embodiment, selector member housing **242** is retained in its first position by a tear strip **252** that is removably receivable between a circumferentially extending rib **242***a* formed on housing **242** and the upper extremity **250***b* of guide sleeve **250**. When the tear strip **252** is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **78** and in so doing will cause the penetrating member **280** to pierce the membrane **282** as well as the closure wall **274** in the manner shown in FIG. **78**. Piercing of the membrane **282** and the closure wall **274** opens a fluid communication path from reservoir **277** to the rate control assembly **104** via a central fluid passageway **280***a* formed in penetrating member **280**. From passageway **280***a*, fluid will flow through conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector

member housing **242**, inlet passageway **144***a* can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **242**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member **242**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length, width and geometry that is formed in rate control plate **110**.

Referring to FIGS. **83** through **87**, yet another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **302**. This alternate form of dispensing device is similar in most respects to that shown in FIGS. **77** through **82** and like numerals are used in FIGS. **83** through **87** to identify like components. The major difference between this latest embodiment of the invention and that shown in FIGS. **77** through **82** resides in the differently configured reservoir defining container **304**. As shown in FIG. **85** container **304**, rather than being in the nature of the collapsible bottle, comprises a reservoir defining container formed as a unitary structure having a bellows-like sidewall **304***a* that is movable from the expanded, starting configuration shown in FIG. **83** to the collapsed configuration shown in FIG. **84**. This important reservoir defining container here includes, in addition to sidewall **304***a*, an interconnected bottom wall **304***b*, an interconnected top wall **304***c* and an interconnected neck portion **304***d* which is sealed at the time of manufacture by an integrally formed, thin closure wall **305**. Neck portion **304***d* which is preferably integrally formed with top wall **304***c*, forms a part of the novel reservoir access means of the invention. Collapsible container **304** defines a fluid reservoir **307** that, in a manner presently to be described, is accessible via a penetrating member **280** that is adapted to pierce closure wall **305** as well as a pierceable membrane **306** which is positioned over closure wall **305** of by means of a closure cap **309** which is affixed to the neck portion **304***d* of container assembly **304** (see also FIG. **87**).

As best seen in FIGS. **83** and **84** the supporting structure **264** is substantially identical to the supporting structure of the last described embodiment and here comprises a connector assembly **266** and a generally cylindrically shaped outer housing **268** that is interconnected with the connector assembly in the manner best seen in FIG. **83** of the drawings.

Disposed within outer housing **268** is the carriage assembly **58**, which is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **58** is the previously described reservoir defining container **304**.

As in the last described embodiment of the invention, closure wall **305** is sealably interconnected with neck portion **304***d* in accordance with the previously described aseptic blow-fill-seal technique. As in the last described embodiment of the invention, the basic container **304** is formed using the earlier described aseptic blow-fill-seal technique and the reservoir portion of the container is sealed by the thin closure wall **305**. The piercable membrane **306** is then positioned over the closure wall **305** and the cap **309** is positioned over the piercable membrane and secured to the integrally formed neck portion **304***d* by any suitable means such as adhesive bonding or sonic welding.

As before, novel guide means are provided for guiding travel of carriage assembly **58** between the first position shown in FIG. **83** and the second position shown in FIG. **84**. This important guide means is of identical construction and operation to that previously described herein.

Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled spring **80**, which is also identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **268***a* of the outer housing **268**, spring **80** will move from its compressed position shown in FIG. **83** to its expanded position shown in FIG. **84** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **83** to its fully deployed or extended position shown in FIG. **84**. As the carriage assembly moves toward its deployed position, the accordion-like, collapsible sidewall **304***a* of the collapsible container **304** will move into the collapsed configuration shown in FIG. **84**. As the container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **307** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. These important flow control means are identical to those previously described in connection with the embodiment of FIGS. **77** through **82** and will not here be further discussed.

As in the last described embodiment, selector member housing **242** is retained in its first position by a tear strip **252** that is removably receivable between a circumferentially extending rib **242***a* formed on housing **242** and the upper extremity **250***b* of guide sleeve **250**. When the tear strip **252** is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **84** and in so doing will cause the penetrating member **280** to pierce the membrane **306** as well as the closure wall **305**. Piercing of the membrane **306** and the closure wall **305** opens a fluid communication path from reservoir **307** to the rate control assembly **104** via a central fluid passageway **280***a* formed in septum penetrating member **280**. From passageway **280***a*, fluid will flow through conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector member housing **242**, inlet passageway **144***a* can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **242**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member **242**. Since outlet passageway **148** is in fluid communication with the administration set

82 of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length that is formed in rate control plate **110**.

Turning next to FIGS. **88** through **91**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **312**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **83** through **87** and like numerals are used in FIGS. **88** through **91** to identify like components. As best seen in FIGS. **88** and **89**, the supporting structure **314** is similar in many respects to supporting structure **214** and here comprises a connector assembly **316** and a generally cylindrically shaped outer housing **318** that is interconnected with the connector assembly in the manner best seen in FIG. **88** of the drawings.

Disposed within outer housing **318** is the carriage assembly **58**, which is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **58** is a reservoir defining assembly **320**, which is of a somewhat different construction. This important reservoir defining assembly here includes a collapsible container assembly **322** having a sidewall **322***a*, an interconnected bottom wall **322***b* and an interconnected top wall **322***c*. Connected to top wall **322***c* and extending therefrom, is a Luer-like connector **324** having external threads **324***a* and a sealing wall **324***b*. Connector **324**, which is interconnected with top wall **322***c* is integrally formed and sealably interconnected at the time of manufacture of the collapsible container assembly **322**, forms a part of the novel reservoir access means of this latest form of the invention. Collapsible container assembly **322** defines a fluid reservoir **327** that, in a manner presently to be described, is accessible via a slightly differently configured penetrating member **330** that is adapted to pierce top sealing wall **322***s* and sealably engage tapered sealing wall **324***b* (FIGS. **88** and **91**).

In the preferred form of this latest alternate embodiment of the invention, Luer-like connector **324** is sealably interconnected with top wall **322***c* in accordance with the previously described aseptic blow-fill-seal technique.

As previously mentioned, the primary differences between this latest form of dispensing device of the invention and those previously described herein resides in the somewhat differently configured container assembly **322** and the somewhat differently configured penetrating member **330**. In constructing the container assembly **322**, the basic container is formed as a unitary structure using the aseptic blow-fill-seal technique earlier described herein and the reservoir portion of the container is sealed by the interconnected walls of the container and integral sealing wall **322***s*.

As in the earlier described embodiments of the invention, novel guide means are provided for guiding travel of carriage assembly **58** between the first position shown in FIG. **88** and the second position shown in FIG. **89**. This important guide means is of identical construction and operation to that previously described herein.

Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled spring **80**, which is also identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **318***b* of the outer housing **318**, spring **80** will move from its retracted position shown in FIG. **88** to its expanded position shown in FIG. **89** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **88** to its fully deployed or extended position shown in FIG. **89**. As the carriage assembly moves toward its deployed position, the collapsible sidewall **322***a* of the collapsible container **322** will move into the collapsed configuration shown in FIGS. **89** and **89**A. As the collapsible container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom through fluid passageway **330***d* formed in the penetrating member **330**.

To further control the flow of medicinal fluid from reservoir **327** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. These components are, in this latest embodiment of the invention, substantially identical in construction and operation to those described in connection with Figure drawings **63** through **76**. As previously mentioned, the penetrating member **330** is of a slightly different construction that is better suited for penetrating top wall **322***s* of the container assembly. More particularly, penetrating member **330** has a generally cylindrically shaped body portion **330***a*, an intermediate tapered portion **330***b* and a reduced diameter penetrating extremity **330***c*. Tapered portion **330***b* engages tapered sealing wall **324***b* forming a substantially fluid seal.

The rate control means of this latest form of the invention is identical in construction and operation to that previously described in connection with Figure drawings **36** through **74**A.

Penetrating member **330** comprises a part of the previously described penetrating assembly, which is generally designated in FIGS. **88** and **89** by the numeral **288**. Support member **316** includes a guide passageway **317**, which guides the travel of the penetrating member **330**. Assembly **288** also includes a cavity **288***a*, which closely receives a portion of the rate control assembly **104**.

In this latest embodiment of the invention, selector member housing **242**, along with assembly **288** is movable from the first position shown in FIG. **88** to the second position shown in FIG. **89**. In addition to guiding the travel of member **242**, guide sleeve **250** defines a cylindrical space **250***a* about which the administration line **82***a* of the administration set **82** can be coiled in the manner best seen in FIG. **88**.

As in the earlier described embodiment, selector member housing **242** is retained in its first position by a tear strip **252** that is removably receivable between a circumferentially extending rib **242***a* formed on housing **242** and the upper extremity **250***b* of guide sleeve **250**. When the tear strip **252** is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **89** and in so doing will cause the penetrating member **330** to pierce upper wall **322***s* in the manner shown in FIG. **89**. Piercing of wall **322***s* opens a fluid communication path from reservoir **327** to the rate control assembly **104** via a central fluid passageway **330***d* formed in septum penetrating member **330**. From passageway **330***d*, fluid will flow through conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate of control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate

control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector member housing **242**, inlet passageway **144***a* can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **242**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member **242**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length that is formed in rate control plate **110**.

Turning next to FIGS. **92** through **96**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **332**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **88** through **91** and like numerals are used in FIGS. **92** through **96** to identify like components.

The major difference between this latest embodiment of the invention and that shown in FIGS. **88** through **91** resides in the differently configured reservoir defining container **334**. As shown in FIG. **92**, container **334**, rather than being in the nature of the collapsible bottle, comprises a reservoir defining unitary container having a bellows-like sidewall **334***a* that is movable from the expanded, starting configuration shown in FIG. **92** to the collapsed configuration shown in FIG. **93**. This important reservoir defining container here includes, in addition to sidewall **334***a*, an interconnected bottom wall **334***b*, and an interconnected top wall **334***c*.

Connected to top wall **334***c* and extending therefrom, is a Luer-like connector **337** having external threads **337***a* and a tapered sealing wall **337***b*. Connector **337**, which forms a part of the novel reservoir access means of this latest form of the invention, is interconnected with top wall **334***c* at the time of manufacture of the collapsible container assembly **334**. Collapsible container **334** defines a fluid reservoir **337** that is accessible via a penetrating member **330** that is similar to the penetrating member previously described in connection with FIGS. **88** and **89** and is adapted to pierce closure wall **335** in the manner previously described. It is to be noted that tapered portion **330***b* of the penetrating member engages the tapered wall **337***b* of container **337** to form a substantially fluid seal.

As indicated in FIGS. **92** and **93** the supporting structure **316** is substantially identical to the supporting structure of the last described embodiment. Similarly, the carriage assembly **58** which is carried within cylindrically shaped outer housing **318** is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **58** in the manner illustrated in FIG. **92** is the previously described reservoir defining container **334**.

As in the last described embodiment of the invention, closure wall **335** is sealably interconnected with neck portion **337** in accordance with the previously described aseptic blow-fill-seal technique. As before, the basic container **334** is formed using the earlier described aseptic blow fill technique and the reservoir portion of the container is sealed by the thin closure wall **335**.

Once again, in order to controllably move the carriage assembly **58** from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **58**, is here provided in the form of a coiled spring **80**, which is also identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **318***b* of the outer housing **318**, spring **80** will move from its compressed position shown in FIG. **92** to its expanded position shown in FIG. **93** and in so doing will controllably move the carriage assembly from its starting position to its fully deployed or extended position as shown in FIG. **93**. As the carriage assembly moves toward its deployed position, the accordion-like, collapsible sidewall **334***a* of the collapsible container **334** will move into the collapsed configuration shown in FIG. **93**. As the container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **337** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. These important flow control means are identical to those previously described in connection with the embodiment of FIGS. **88** through **91** and will not here be further discussed.

As in the last described embodiment, selector member housing **242** is retained in its first position by a tear strip **252**. When the tear strip **252** is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **93** and in so doing will cause the penetrating member **330** to pierce the closure wall **335** and sealably engage sealing wall **337***b*.

Piercing of the closure wall **335** opens a fluid communication path from reservoir **337** to the rate control assembly **104** via a central fluid passageway **330***d* formed in penetrating member **330**. From passageway **330***d*, fluid will flow through conventional particulate filter **139**, into inlet **140** of rate control cover **106** of the rate control assembly **104**, into inlet **141** of rate control plate **110** and then into the various circuitous fluid channels of the rate control plate in the manner previously described. The fluid will then flow into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector member housing **242**, inlet passageway **144***a* can be selectively brought into index with one of the radial extensions **147** of the axially extending passageways formed in selector member **242**, thereby providing fluid communication between outlet passageway **148** and the selected one of the circuitous flow passageways formed in rate control plate **110** via annular passageway **151** and the selected axially extending passageway formed in the selector member **242**. Since outlet passageway **148** is in fluid communication with the administration set **82** of the invention via passageway **151**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length that is formed in rate control plate **110**.

Turning next to FIGS. **97** through **101**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **342**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **88** through **91** and like numerals are used in FIGS. **97** through **101** to identify like components.

The difference between this latest embodiment of the invention and that shown in FIGS. **88** through **91** resides in the slightly differently configured reservoir defining container **344** and the slightly differently configured penetrating assembly **346**. As shown in FIG. **97** container **344** is similar in most respects to container **322** of FIG. **88** save that the a Luer-like connector **347** has external threads **347***a* and is provided with a differently configured sealing wall **349** for sealably engaging the slightly differently configured penetrating member **346***a* of penetrating assembly **346**.

Reservoir defining container **344** has sidewall **344***a* that is movable from the expanded, starting configuration shown in FIG. **97** to the collapsed configuration shown in FIG. **98**. This important reservoir defining container here includes, in addition to sidewall **344***a*, an interconnected bottom wall **344***b*, an interconnected top wall **344***c* to which Luer-like connector **347** is attached. Luer-like connector **347** here forms a part of the novel reservoir access means of the invention.

Collapsible unitary container **344** defines a fluid reservoir **351** that is accessible via penetrating member **346***a*. Penetrating member **346***a* here comprises an elongated body portion **353** and a reduced diameter penetrating portion **355** that is adapted to pierce closure wall **347***b* of Luer-like connector **347** in the manner shown in FIG. **98**. After penetrating portion **355** pierces closure wall **347***b*, the tapered interconnection wall **357**, which interconnects body portion **353** and reduced diameter penetrating portion **355**, sealably engages sealing wall **349** in the manner shown in FIG. **98**.

Except for the differently configured collapsible container **344** and the differently configured penetrating member **346***a*, the apparatus of this latest form of the invention, including the carriage assembly **58**, the locking means, the stored energy source and a flow control means operate in the same manner to accomplish the same result as the apparatus discussed in connection with FIGS. **88** through **91**.

Turning next to FIGS. **102** through **106**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **362**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **97** through **101** and like numerals are used in FIGS. **102** through **106** to identify like components.

The difference between this latest embodiment of the invention and that shown in FIGS. **97** through **101** resides only in the differently configured reservoir defining container **364**. As shown in FIG. **102** container **364**, rather than being in the nature of the collapsible bottle, comprises a reservoir defining container having a bellows-like sidewall **364***a* that is movable from the expanded, starting configuration shown in FIG. **102** to the collapsed configuration shown in FIG. **103**. This important reservoir defining container here includes, in addition to sidewall **364***a*, an interconnected bottom wall **364***b*, and an interconnected top wall **364***c*.

Connected to top wall **364***c* and extending therefrom, is a Luer-like connector **367** having external threads **367***a* and a sealing wall **367***b*. Connector **367**, which is interconnected with top wall **364***c* at the time of manufacture of the collapsible container assembly **364**, here forms a part of the novel reservoir access means of the invention.

Collapsible unitary container **364** defines a fluid reservoir **367** that is accessible via a penetrating member **346***a* that is identical to the penetrating member previously described in connection with FIGS. **97** and **98** and is adapted to pierce closure wall **367***b* in the manner previously described.

Except for the differently configured collapsible container **364**, the apparatus of this latest form of the invention, including the carriage assembly **58**, the locking means, the stored energy source and a flow control means operate in the same manner to accomplish the same result as the apparatus discussed in connection with FIGS. **97** through **101**.

Referring now to FIGS. **107** through **111**, yet another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **372**. This alternate form of dispensing device is similar in many respects to that shown in FIGS. **97** through **101** and like numerals are used in FIGS. **107** through **111** to identify like components.

The difference between this latest embodiment of the invention and that shown in FIGS. **97** through **101** resides in the slightly differently configured reservoir defining unitary container **374** and the slightly differently configured penetrating assembly **376**. As shown in FIG. **107** container **374** is similar in most respects to container **344** of FIG. **97**, save that a Luer-like connector **377** is provided with a differently configured sealing wall **379** for sealably engaging the slightly differently configured penetrating member **376***a* of penetrating assembly **376**. Luer-like connector **377** here forms a part of the novel reservoir access means of the invention.

Reservoir defining container **374** has sidewall **374***a* that is movable from the expanded, starting configuration shown in FIG. **107** to the collapsed configuration shown in FIG. **108**. This important reservoir defining container here includes, in addition to sidewall **374***a*, an interconnected bottom wall **374***b*, an interconnected top wall **374***c* to which Luer-like connector **377** is attached.

Collapsible container **374** defines a fluid reservoir **381** that is accessible via a punch like penetrating member **376***a*. Penetrating member **376***a* here, rather than comprising an elongated body portion and a reduced diameter penetrating portion, comprises a uniform diameter, blunt ended member having an annular cutting element **376***c* that is adapted to pierce closure wall **379** of Luer-like connector **377** in the manner shown in FIG. **108**. After penetrating closure wall **379**, portion **376***a*, sealably engages sealing wall **379** in the manner shown in FIG. **108**.

Except for the differently configured collapsible container **374** and the differently configured penetrating assembly **376**, the apparatus of this latest form of the invention, including the carriage assembly **58**, the locking means, the stored energy source and a flow control means operate in the same manner to accomplish the same result as the apparatus discussed in connection with FIGS. **97** through **101**.

Turning next to FIGS. **112** through **116**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **382**. This alternate form of dispensing device is similar in most respects to that shown in FIGS. **107** through **111** and like numerals are used in FIGS. **112** through **116** to identify like components.

The difference between this latest embodiment of the invention and that shown in FIGS. **107** through **111** resides only in the differently configured reservoir defining unitary container **384**. As shown in FIG. **112** container **384**, rather than being in the nature of the collapsible bottle, comprises a reservoir defining container having a bellows-like sidewall **384***a* that is movable from the expanded, starting configuration shown in FIG. **112** to the collapsed configuration shown in FIG. **113**. This important reservoir defining container here includes, in addition to sidewall **384***a*, an interconnected bottom wall **384***b*, and an interconnected top wall **384***c*.

Connected to top wall **384***c* and extending therefrom, is a Luer-like connector **387** having external threads **387***a* and a sealing wall **387***b*. Connector **387**, which is interconnected with top wall **384***c* at the time of manufacture of the collaps-

ible container assembly **384**, here forms a part of the novel reservoir access means of the invention.

Collapsible container **384** defines a fluid reservoir **389** that is accessible via a penetrating member **376***a* that is identical to the penetrating member previously described in connection with FIGS. **107** and **108** and is adapted to pierce closure wall **387***b* in the manner previously described.

Except for the differently configured collapsible container **384**, the apparatus of this latest form of the invention, including the carriage assembly **58**, the locking means, the stored energy source and a flow control means operate in the same manner to accomplish the same result as the apparatus discussed in connection with FIGS. **107** through **111**.

Referring next to FIGS. **117** through **122**, still another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **392**. This alternate form of dispensing device is similar in some respects to the earlier described embodiments shown in FIGS. **77** through **82** and like numerals are used in FIGS. **117** through **122** to identify like components.

The primary difference between this latest form of dispensing device and that previously described in connection with FIGS. **77** through **82** resides in the provision of a novel stored energy source, which is of a totally different construction. More particularly, rather than being in the form of a coil spring, the novel stored energy means of this latest form of the invention comprises a compressible, expandable sponge-like configuration, which is generally designated in the drawings by the numeral **394**. This unique stored energy source, which functions to move a carriage **396** from the first compressed position shown in FIG. **117** to the second expanded position shown in FIG. **118** can take several forms. By way of non-limiting example, stored energy source **394** can comprise a micro porous, malodorous, macro-porous, ordered structure and can be constructed from Polypropylene (PP), Ultra High Molecular Weight Polyethylene (UHMWPE), High Density Polyethylene (HDPE), Polyvinylidene Fluoride (PVDF), Ethyle-vinyl Acetate (EVA), Styrene Acrylonitrile (SAN), Polytetrafluroethylene (PTFE) and porous cellulose acetate. A suitable source of these materials is Porex Technologies of Fairburn, Ga. However, practice has shown that any porous plastic material including an open cell, porous sponge material is suitable for use in constructing the stored energy source.

As in the embodiment of the invention shown in FIG. **77**, the reservoir defining assembly **270** here comprises a collapsible container assembly **272**, which is of identical construction that previously described and is carried by carriage assembly **396** in the manner illustrated in FIG. **117**.

As before, the carriage assembly **396** is releasably secured to base portion **268***a* of the outer housing **268** by a novel locking means. When the locking means of the invention is manipulated in a manner to unlock the carriage assembly **396** from the base portion **268***a*, sponge **394** will expand from the first compressed position shown in FIG. **117** to the second expanded position shown in FIG. **118** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **117** to its more fully deployed or extended position shown in FIG. **118**. As the carriage assembly moves toward its deployed position, the sidewall **272***a* of the collapsible container **272** will move into the collapsed configuration shown in FIG. **118**. As the collapsible container collapses, the medicinal fluid contained within the container reservoir **277** will be controllably urged outwardly thereof.

To control the flow of medicinal fluid from reservoir **277** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. Both the operating means and the rate control means of this latest form of the invention are identical in construction and operation to those described in connection with the embodiment of FIGS. **77** through **82**.

As in the earlier described embodiment, the selector member housing **242** is retained in its first position by a tear strip **252**. When the tear strip is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly **288** into the second position shown in FIG. **118** and in so doing will cause the penetrating member **280** to pierce the membrane **282** as well as the closure wall **274** in the manner shown in FIG. **118**. Piercing of the membrane **282** and the closure wall **274** opens a fluid communication path from reservoir **277** to the rate control assembly **104** via a central fluid passageway **280***a* formed in penetrating member **280**. From reservoir **277**, the fluid will flow through central fluid passageway **280***a* of penetrating member **280**, through conventional particulate filter **139**, through the rate control assembly **104**, through the selector member **116** and toward the patient via the administration set **82**.

Referring next to FIGS. **123** through **127**, yet another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **402**. This alternate form of dispensing apparatus is similar in most respects to that shown in FIGS. **117** through **122** and like numerals are used in FIGS. **123** through **127** to identify like components. The major difference between this latest embodiment of the invention and that shown in FIGS. **117** through **122** resides in the differently configured reservoir defining container **404**.

As shown in FIGS. **123** and **126**, container **404**, rather than being in the nature of a collapsible bottle, comprises a reservoir defining container having a bellows-like sidewall **404***a* that is movable from the expanded, starting configuration shown in FIG. **123** to the collapsed configuration shown in FIG. **124**. This important reservoir defining container here includes, in addition to sidewall **404***a*, an interconnected bottom wall **404***b*, an interconnected top wall **404***c* and an interconnected neck portion **404***d*, which is sealed at the time of manufacture by a thin closure wall **405**. Neck portion **404***d* forms a part of the novel reservoir access means of the invention. Collapsible container **404** defines a fluid reservoir **407** that is accessible via a penetrating member **280** that is identical to that previously described. Penetrating member **280** is adapted to pierce closure wall **405** as well as a pierceable membrane **282**, which is positioned over closure wall **405** of by means of a closure cap **284**, which is affixed to the neck portion **404***d* of container assembly **404**.

As best seen in FIGS. **123** and **124** the supporting structure is substantially identical to the supporting structure of the last described embodiment and here comprises a connector assembly **266** and a generally cylindrically shaped outer housing **268** that is interconnected with the connector assembly in the manner best seen in FIG. **123** of the drawings.

Disposed within outer housing **268** is the carriage assembly **396**, which is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein.

Carried by carriage assembly is the previously described reservoir defining container **404**.

As in the last described embodiment of the invention, closure wall **405** is sealably interconnected with neck portion **404***d* in accordance with the previously described aseptic blow-fill-seal technique. As before, the basic container **404** is formed using the earlier described aseptic blow-fill-seal technique and the reservoir portion of the container is sealed by the thin closure wall **405**. The piercable membrane **282** is then positioned over the closure wall **405** and the cap **284** is positioned over the piercable membrane and secured to neck portion **404***d* by any suitable means such as adhesive bonding or sonic welding.

Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **396**, is here provided in the form of a compressible, expandable sponge-like configuration **394**, which is identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **268***a* of the outer housing **268**, sponge **394** will expand and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **123** to its fully deployed or extended position shown in FIG. **124**. As the carriage assembly moves toward its deployed position, the sidewall **404***a* of the collapsible container **404** will move into the collapsed configuration shown in FIG. **124**. As the collapsible container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To control the flow of medicinal fluid from reservoir **407** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. Both the operating means and the rate control means of this latest form of the invention are identical in construction and operation to those described in connection with the embodiment of FIGS. **117** and **118**.

As in the earlier described embodiment, selector member housing **242** is retained in its first position by a tear strip **252**. When the tear strip is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **124** and in so doing will cause the penetrating member **280** to pierce the membrane **282** as well as the closure wall **405** in the manner shown in FIG. **124**. Piercing of the membrane **282** and the closure wall **405** opens a fluid communication path from reservoir **407** to the rate control assembly **104** via a central fluid passageway **280***a* formed in penetrating member **280**. From reservoir **407**, the fluid will flow through central fluid passageway **280***a* of penetrating member **280**, through conventional particulate filter **139**, through the rate control assembly **104**, through the selector member **116** and toward the patient via the administration set **82**.

Turning next to FIGS. **128** through **132**, yet another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **412**. This alternate form of dispensing apparatus is similar in many respects to that shown in FIGS. **123** through **126** and like numerals are used in FIGS. **128** through **132** to identify like components. As best seen in FIGS. **128** and **129** the supporting structure **414** is similar in many respects to supporting structure **264** of FIGS. **123** and **124** and here comprises a connector assembly **416** and a generally cylindrically shaped outer housing **418** that is interconnected with the connector assembly in the manner best seen in FIG. **128** of the drawings.

Disposed within outer housing **418** is the carriage assembly **396**, which is of identical construction and operation to that described in connection with the preceding embodiment and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly **396** is a reservoir defining assembly **420**, which is of a somewhat different construction. This important reservoir defining assembly here includes a collapsible container assembly **420** having a sidewall **420***a*, an interconnected bottom wall **420***b* and an interconnected top wall **420***c*. Connected to top wall **420***c* and extending therefrom, is a Luer-like connector **422** having external threads **422***a* and a sealing wall **422***b*. Connector **422**, which is interconnected with top wall **420***c* at the time of manufacture of the collapsible container assembly, forms a part of the novel reservoir access means of this latest form of the invention. Collapsible container assembly **420** defines a fluid reservoir **425** that is accessible via a penetrating member **280** that is identical to that previously described and is adapted to pierce the closure wall **422***c* of Luer-like connector **422** and sealably engage a sealing wall **422***b* formed on connector **422**.

In the preferred form of this latest alternate embodiment of the invention, Luer-like connector **422** is integrally formed and sealably interconnected with top wall **420***c* in accordance with the previously described aseptic blow-fill-seal technique. In order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **396**, is here provided in the form of a compressible, expandable sponge-like configuration **394**, which is identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **418***a* of the outer housing **418**, sponge **394** will expand from its first compressed position shown in FIG. **128** to its second, more expanded position shown in FIG. **129** and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **128** to its fully deployed or extended position shown in FIG. **129**. As the carriage assembly moves toward its deployed position, the collapsible sidewall **420***a* of the collapsible container **420** will move into the collapsed configuration shown in FIG. **129**. As the container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To further control the flow of medicinal fluid from reservoir **425** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. These important flow control means are identical to those previously described in connection with the embodiment of FIGS. **122** and **123** and will not here be further discussed.

As in the last described embodiment, selector member housing **242** is retained in its first position by a tear strip **252**. When the tear strip **252** is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly **288** into the second position shown in FIG. **129** and in so doing will cause the penetrating member **280** to penetrate top wall **422***c* of the Luer-like connector **422**.

Piercing of wall **422***c* opens a fluid communication path from reservoir **425** to the rate control assembly **104** via a central fluid passageway **280***a* formed in penetrating member **280**. From passageway **280***a*, fluid will flow through conventional particulate filter **139**, into the inlet of the rate of control assembly **104** and into the circumferentially spaced-apart fluid passageways formed in the selector housing **242**. In operating the device in the manner previously described herein, by rotating the selector member **116**, which is carried by selector member housing **242**, the rate of fluid flow toward the patient can be precisely controlled by selecting a rate control passageway of appropriate length, width and geometry that is formed in rate control plate **110**.

Turning next to FIGS. **133** and **134**, yet another form of the dispensing device of the present invention for dispensing medicaments to a patient is there shown and generally designated by the numeral **422**. This alternate form of dispensing apparatus is similar in many respects to that shown in FIGS. **128** through **132** and like numerals are used in FIGS. **133** and **134** to identify like components. The major difference between this latest embodiment of the invention and that shown in FIGS. **128** through **132** resides in the differently configured reservoir defining container **424**.

As shown in FIGS. **133** and **134**, container **424**, rather than being in the nature of the collapsible bottle, comprises a reservoir defining container having a bellows-like sidewall **424***a* that is movable from the expanded, starting configuration shown in FIG. **133** to the collapsed configuration shown in FIG. **134**. This important reservoir defining container here includes, in addition to sidewall **424***a*, an interconnected bottom wall **424***b*, an interconnected top wall **424***c* and an interconnected neck portion **424***d*, which is integrally formed and sealed at the time of manufacture by a thin closure wall **425**. Neck portion **424***d* forms a part of the novel reservoir access means of the invention. Collapsible container **424** defines a fluid reservoir **427** that is accessible via a penetrating member **280** that is identical to that previously described. Penetrating member **280** is adapted to pierce closure wall **425** in the manner shown in FIG. **134**.

The supporting structure **414** is substantially identical to the supporting structure of the last described embodiment and here comprises a connector assembly **416** and a generally cylindrically shaped outer housing **418** that is interconnected with the connector assembly in the manner best seen in FIG. **133** of the drawings.

Disposed within outer housing **418** is the carriage assembly **396**, which is of identical construction and operation to that previously described and is releasably locked in its first position by locking means also identical in construction and operation to the locking means previously described herein. Carried by carriage assembly is the previously described reservoir defining container **424**.

As in the last described embodiment of the invention, closure wall **425** is sealably interconnected with neck portion **424***d* in accordance with the previously described aseptic blow-fill-seal technique. Once again, in order to controllably move the carriage assembly from its first position to its second position, novel stored energy means are provided. This novel stored energy means, which is operably associated with carriage assembly **396**, is here provided in the form of a compressible, expandable sponge-like configuration **394**, which is identical in construction and operation to that previously described.

As in the earlier described embodiments of the invention, when the locking means of the invention is manipulated in a manner to unlock the carriage assembly from base portion **418***a* of the outer housing **418**, sponge **394** will expand and in so doing will controllably move the carriage assembly from its starting position shown in FIG. **133** to its fully deployed or extended position shown in FIG. **134**. As the carriage assembly moves toward its deployed position, the sidewall **424***a* of the collapsible container **424** will move into the collapsed configuration shown in FIG. **134**. As the collapsible container collapses, the medicinal fluid contained within the container will be controllably expelled therefrom.

To control the flow of medicinal fluid from reservoir **427** toward the administration set **82** of the invention and then on to the patient, flow control means are provided. Once again, this novel fluid flow control means, comprises two cooperating components, namely a rate control means for controlling the rate of fluid flow from the collapsible reservoir and an operating means for controlling fluid flow between the collapsible reservoir and the rate control means. Both the operating means and the rate control means of this latest form of the invention are identical in construction and operation to those described in connection with the embodiment of FIGS. **128** and **129**.

As in the earlier described embodiment, selector member housing **242** is retained in its first position by a tear strip **252**. When the tear strip is removed, a rotary force exerted on selector member housing **242** will move the housing along with the penetrating assembly into the second position shown in FIG. **134** and in so doing will cause the penetrating member **280** to pierce the closure wall **425** in the manner shown in FIG. **134**. Piercing of the closure wall **425** opens a fluid communication path from reservoir **427** to the rate control assembly **104** via a central fluid passageway **280***a* formed in penetrating member **280**. From reservoir **427**, the fluid will flow through central fluid passageway **280***a* of penetrating member **280**, through conventional particulate filter **139**, through the rate control assembly **104**, through the selector member **116** and toward the patient via the administration set **82**.

Having now described the invention in detail in accordance with the requirements of the patent statutes, those skilled in this art will have no difficulty in making changes and modifications in the individual parts or their relative assembly in order to meet specific requirements or conditions. Such changes and modifications may be made without departing from the scope and spirit of the invention, as set forth in the following claims.

The invention claimed is:

1. A dispensing device for dispensing medicaments to a patient comprising:

(a) a supporting structure;

(b) a pre-filled collapsible container having a continuous wall formed of a single material carried by said supporting structure, said collapsible container comprising an hermetically sealed reservoir, including an accordion-like member, said hermetically sealed reservoir having an outlet port and including sealing means for sealing said outlet port, said sealing means comprising a nipple connected to said accordion-like member, said nipple having a severable tip portion;

(c) stored energy means carried by said supporting structure and operably associated with said collapsible reservoir for collapsing said collapsible reservoir to expel fluid therefrom;

(d) an administration set, including an administration line interconnected with said outlet of said collapsible reservoir; and

(e) fluid flow control means carried by said supporting structure for controlling fluid flow from said collapsible reservoir toward said administration set, said fluid flow

control means comprising rate control means carried by said supporting structure for controlling the rate of fluid flow from said collapsible reservoir toward said administration set and operating means carried by said supporting structure for controlling fluid flow between said collapsible container and said rate control means, said operating means comprising an operating shaft rotatably carried by said supporting structure, said operating shaft carrying a knife for severing said tip portion of said nipple.

2. The dispensing device as defined in claim **1** in which said stored energy means comprises an expandable sponge operably interconnected with said collapsible reservoir.

3. A dispensing device for dispensing medicaments to a patient comprising:

(a) a supporting structure comprising a base assembly and a housing interconnected with said base assembly;

(b) a carriage assembly interconnected with said supporting structure for movement between a first position and a second position;

(c) a unitary pre-filled collapsible container comprising a bellows structure and having an uninterrupted wall carried by said carriage assembly, said collapsible container comprising a reservoir having an outlet port and including sealing means for sealing said outlet port, said sealing means comprising a nipple connected to said uninterrupted wall, said nipple having a severable tip portion;

(d) a stored energy means operably associated with said carriage assembly for moving said carriage assembly between said first and second positions, said stored energy means comprising a spring;

(e) an administration set, including an administration line interconnected with said outlet port of said collapsible reservoir; and

(f) fluid flow control means carried by said base assembly of said supporting structure for controlling fluid flow from said collapsible reservoir toward said administration set, said fluid flow control means comprising:

(i) rate control means carried by said supporting structure for controlling the rate of fluid flow from said collapsible reservoir toward said administration set; and

(ii) operating means carried by said supporting structure for controlling fluid flow between said collapsible container and said rate control means, said operating means comprising an operating shaft rotatably carried by said base assembly of said supporting structure for movement between a first position blocking fluid flow from said collapsible reservoir toward said administration set and a second position permitting fluid flow from said collapsible reservoir toward said administration set, said operating shaft carrying a knife having a cutting edge for severing said tip portion of said nipple.

4. A dispensing device for dispensing medicaments to a patient comprising:

(a) a supporting structure comprising a base assembly and a housing interconnected with said base assembly;

(b) a carriage assembly interconnected with said supporting structure for movement between a first position and a second position;

(c) a unitary pre-filled collapsible container having an uninterrupted wall carried by said carriage assembly, said collapsible container comprising a reservoir having an outlet port, said uninterrupted wall including an accordion-like member and including sealing means for sealing said outlet port, said sealing means comprising a nipple connected to said accordion-like member, said nipple having a sealed, severable tip portion;

(d) a stored energy means operably associated with said carriage assembly for moving said carriage assembly between said first and second positions, said stored energy means comprising a spring;

(e) an administration set, including an administration line interconnected with said outlet port of said collapsible reservoir; and

(f) fluid flow control means carried by said base assembly of said supporting structure for controlling fluid flow from said collapsible reservoir toward said administration set, said fluid flow control means comprising:

(i) rate control means carried by said supporting structure for controlling the rate of fluid flow from said collapsible reservoir toward said administration set; and

(ii) operating means carried by said supporting structure for controlling fluid flow between said collapsible container and said rate control means, said operating means comprising an operating shaft rotatably carried by said base assembly of said supporting structure for movement between a first position blocking fluid flow from said collapsible reservoir toward said administration set and a second position permitting fluid flow from said collapsible reservoir toward said administration set, said operating shaft having a body portion having a cavity located to receive said severable tip portion of said nipple.

5. A dispensing device for dispensing medicaments to a patient comprising:

(a) a supporting structure comprising a base assembly and a housing interconnected with said base assembly;

(b) a carriage assembly interconnected with said supporting structure for movement between a first position and a second position;

(c) a unitary pre-filled collapsible container having an uninterrupted wall carried by said carriage assembly said uninterrupted wall including an accordion-like member, said collapsible container being integrally formed and comprising a reservoir having an outlet port, said outlet port being closed by a frangible member comprising a nipple connected to said accordion-like member, said nipple having a sealed, severable tip portion;

(d) a stored energy means operably associated with said carriage assembly for moving said carriage assembly between said first and second positions, said stored energy means comprising a spring;

(e) an administration set, including an administration line interconnected with said outlet port of said collapsible reservoir; and

(f) fluid flow control means carried by said base assembly of said supporting structure for controlling fluid flow from said collapsible reservoir toward said administration set, said fluid flow control means comprising:

(i) rate control means carried by said supporting structure for controlling the rate of fluid flow from said collapsible reservoir toward set administration set; and

(ii) operating means carried by said supporting structure for controlling fluid flow between said collapsible container and said rate control means, said operating means comprising an operating shaft rotatably carried by said base assembly of said supporting structure for movement between a first position blocking fluid flow

from said collapsible reservoir toward said administration set and a second position permitting fluid flow from said collapsible reservoir toward said administration set, said operating shaft carrying a spring knife having a cutting edge for severing said tip portion of said nipple.

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